### Semiannual Program Review and Facility Inspection Checklist

#### About the checklist

The Semiannual Program Review and Facility Inspection Checklist is provided to assist institutions in conducting their semiannual reviews of programs and facilities for the care and use of animals. The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy), section IV.B.1.-2., requires the Institutional Animal Care and Use Committee (IACUC) to review the institution's program for humane care and use of animals and inspect all of the institution's animal facilities at least once every 6 months using the Guide for the Care and Use of Laboratory Animals: Eighth Edition (Guide) as a basis for evaluation.

#### How to use the checklist

This checklist is a tool to assist IACUCs in conducting thorough semiannual reviews. IACUCs are not required to use this checklist but are encouraged to amend it as necessary to reflect institutional programs and needs, or to develop their own checklist. If the checklist is modified, periodic review of the checklist is recommended to ensure relevant topics are considered as the animal care and use program changes.

The checklist covers the major topics of the *Guide* and the requirements of the PHS Policy. The checklist does not replace the *Guide*, but should be utilized in conjunction with the *Guide*. The *Guide* provides the standards, recommendations, and descriptions of desired outcomes necessary to evaluate and inspect an animal care and use program. Relevant references for the *Guide* and the PHS Policy are noted. Endnotes are included to reference specific U.S. Department of Agriculture (USDA) regulatory requirements that differ from the PHS Policy. Topics that are new to this version of the checklist or identified as a "must" in the *Guide* are highlighted. A column to identify changes that have occurred in the institution's program for animal care and use (PHS Policy IV.A.1.a.-i.) since the last review is also a new feature.

The checklist consists of the following sections:

- I. Semiannual Program Review Checklist
  - Institutional Policies and Responsibilities
  - Veterinary Care
- II. Semiannual Facility Inspection Checklist
  - Terrestrial Animal Housing and Support Areas
  - Aquatic Animal Housing and Support Areas
  - Cagewash
  - Special Facilities: Aseptic Surgery
  - Special Facilities: Procedure Areas, Non-survival Surgeries, Laboratories, Rodent Surgeries, Imaging, Whole Body Irradiation, Hazardous Agent Containment, Behavioral Studies
- III. Semiannual Program Review and Facility Inspection Report
- IV. Endnotes

It is recommended that the Program Review section be completed during an IACUC meeting. Because physical aspects of a program require visual observation to evaluate, it is recommended that the Facility Inspection section be completed during an inspection of the facilities, including satellite facilities.

A table is provided, "Semiannual Program Review and Facility Inspection Report," as a format for the IACUC to organize and track information regarding deficiencies, and plans and schedules for correction. IACUCs may choose to attach the table to the Semiannual Report to the Institutional Official.

### Questions or comments?

Suggestions or comments about this checklist should be e-mailed to: olawdpe@mail.nih.gov.

# I. Semiannual Program Review Checklist i

Institutional Policies and Responsibilities: GLTED

Exemption 6Exemption 6Exemption 6

, and Leslie Jarrell Date: 11/6/2019

1. Animal Care and Use Program 뚸	<b>A</b> *	М	S	С	NA
<ul> <li>Responsibility for animal well-being is assumed by all members of the program (Guide p 1) [must]</li> </ul>	<b>X</b>				
IO has authority to allocate needed resources (Guide, p 13)	X				
<ul> <li>Resources necessary to manage program of veterinary care are provided (Guide, p 14 [must]</li> </ul>					
<ul> <li>Sufficient resources are available to manage the program, including training of personnel in accord with regulations and the Guide (Guide, pp 11, 15)</li> </ul>	X				
<ul> <li>Program needs are regularly communicated to IO by AV and/or IACUC (Guide, p 13)</li> <li>Responsibilities for daily animal care and facility management are assigned to specific individual(s) when a full-time veterinarian is not available on site (Guide, p 14) [must]</li> </ul>					
<ul> <li>Inter-institutional collaborations are described in formal written agreements (Guide, p 15)</li> </ul>	X				
<ul> <li>Written agreements address responsibilities, animal ownership, and IACUC oversight (Guide, p 15)</li> </ul>	X				
2. Disaster Planning and Emergency Preparedness №	$\mathbf{A}^*$	М	S	С	NA
<ul> <li>Disaster plans for each facility to include satellite locations are in place (Guide, p 35, p 75) [must]</li> </ul>	2			X	
Plans include provisions for euthanasia (Guide, p 35) [must]				X	
<ul> <li>Plans include triage plans to meet institutional and investigators' needs (<i>Guide</i>, <u>p 35</u>)</li> <li>Plans define actions to prevent animal injury or death due to HVAC or other failures</li> </ul>				X	
(Guide, p 35)				X	
Plans describe preservation of critical or irreplaceable animals (Guide, p 35)				X	
<ul> <li>Plans include essential personnel and their training (Guide, p 35)</li> <li>Animal facility plans are approved by the institution and incorporated into overall</li> </ul>				X	
<ul> <li>response plan (Guide, p 35)</li> <li>Law enforcement and emergency personnel are provided a copy and integration with overall plan is in place (Guide, p 35)</li> </ul>	X			X	
3. IACUC NEW	<b>A</b> *	м	s	С	NA
Meets as necessary to fulfill responsibilities ( <i>Guide</i> , <u>p 25</u> ) [must]	X				
IACUC Members named in protocols or with conflicts recuse themselves from protocol decisions (Guide, p 26) [must]	X				
Continuing IACUC oversight after initial protocol approval is in place (Guide, p 33)	X				
IACUC evaluates the effectiveness of training programs (Guide, p 15)				X	
4. IACUC Protocol Review - Special Considerations	$\mathbf{A}^*$	М	s	С	NA
Humane endpoints are established for studies that involve tumor models, infectious diseases, vaccine challenge, pain modeling, trauma, production of monoclonal antibodies, assessment of toxicologic effects, organ or system failure, and models of cardiovascular shock (Guide, p 27)	x				
For pilot studies, a system to communicate with the IACUC is in place (Guide, p 28)	X				
For genetically modified animals, enhanced monitoring and reporting is in place (Guide, p 28)	X				
Restraint devices are justified in the animal use protocols (Guide, p 29) [must]					X
<ul> <li>Alternatives to physical restraint are considered (Guide, p 29)</li> </ul>					X

<ul> <li>Multiple surgical procedures on a single animal are justified and outcomes evaluated (Guide, p 30)</li> <li>Major versus minor surgical procedures are evaluated on a case-by-case basis (Guide, p 30)</li> </ul>					X
<ul> <li>Multiple survival procedure justifications in non-regulated species conform to regulated species standards (Guide, p 30)</li> </ul>	i				X
<ul> <li>Animals on food/fluid restriction are monitored to ensure nutritional needs are met (Guide, p 31)</li> <li>Body weights for food/fluid restricted animals are recorded at least weekly (Guide, p</li> </ul>					X
<ul> <li>Daily written records are maintained for food/fluid restricted animals (<i>Guide</i>, p 31)</li> <li>Pharmaceutical grade chemicals are used , when available, for animal-related procedures (<i>Guide</i>, p 31)</li> </ul>				X	X
<ul> <li>Non-pharmaceutical grade chemicals are described, justified, and approved by IACUC (Guide, p 31)</li> <li>Investigators conducting field studies know zoonotic diseases, safety issues, laws and regulations applicable in study area (Guide, p 32)</li> </ul>	X			X	
<ul> <li>Disposition plans are considered for species removed from the wild (<i>Guide</i>, p 32)</li> <li>Toe-clipping only used when no alternative, performed aseptically and with pain relief (<i>Guide</i>, p 75)</li> </ul>	X				X
. IACUC Membership and Functions	<b>A</b> *	М	S	С	NA
<ul> <li>IACUC is comprised of at least 5 members, appointed by CEO (PHS Policy, <u>IV.A.3.</u>)</li> <li>Members include a veterinarian, a scientist, a nonscientist, and a nonaffiliated non-lab animal user (<i>Guide</i>, <u>p 24</u>)<sup>ii</sup></li> </ul>	X				
<ul> <li>IACUC authority and resources for oversight and evaluation of institution's program are provided (<i>Guide</i>, p 14)</li> <li>IACUC conducts semiannual evaluations of institutional animal care and use program</li> </ul>	X				
(PHS Policy, <u>IV.B.</u> )	X				
<ul> <li>Conducts semiannual inspections of institutional animal facilities (PHS Policy, <u>IV.B.</u>)</li> </ul>	X				
<ul> <li>IACUC organizationally reports to the Institutional Official (PHS Policy, <u>IV.A.1.b.</u>)</li> <li>Methods for reporting and investigating animal welfare concerns are in place (<i>Guide</i>, <u>p</u></li> <li><u>[must]</u></li> </ul>	X			X	
<ul> <li>Reviews and investigates concerns about animal care and use at institution<sup>iii</sup> (PHS Policy, <u>IV.B.</u>)</li> <li>Procedures are in place for review, approval, and suspension of animal activities<sup>iv</sup></li> </ul>				X	
<ul> <li>(PHS Policy, <u>IV.B.</u>)</li> <li>Procedures are in place for review and approval of significant changes to approved</li> </ul>	X				
activities (PHS Policy, <u>IV.B.</u> )     Policies are in place for special procedures (e.g., genetically modified animals,	X				
restraint, multiple survival surgery, food and fluid regulation, field investigations, agricultural animals) (Guide, p 27-32)					
					X

	<ul> <li>Training on legislation, regulations, guidelines, and policies (Guide, p 17)</li> </ul>	X				
	<ul> <li>Training on how to inspect facilities and labs where animal use or housing occurs (Guide, p 17)</li> </ul>	X				
		X				
	o Training on how to review protocols as well as evaluate the program ( <i>Guide</i> , <u>p 17</u> )					
	o Ongoing training/education ( <i>Guide</i> , <u>p 17</u> )	X				
7. I <i>l</i>	ACUC Records and Reporting Requirements <sup>vi</sup>	$\mathbf{A}^*$	М	S	C	NA
•	Semiannual report to the IO (PHS Policy, <u>IV.B.</u> )					
	Submitted to IO every 6 months	X				
	<ul> <li>Compiles program review and facility inspection(s) results (includes all program and facility deficiencies)</li> </ul>	X				
	o Includes minority IACUC views	X				
	<ul> <li>Describes IACUC-approved departures from the Guide or PHS Policy and the reasons for each departure<sup>vii</sup></li> </ul>					X
	o Distinguishes significant from minor deficiencies	X				
	o Includes a plan and schedule for correction for each deficiency identified	X				
	<ul> <li>Reports to OLAW (PHS Policy, <u>IV.F.</u>)</li> </ul>					
	<ul> <li>Annual report to OLAW documents program changes, dates of the semiannual program reviews and facility inspections and includes any minority views</li> </ul>	X				
	<ul> <li>Promptly advises OLAW of serious/ongoing Guide deviations or PHS Policy</li> </ul>					v
	noncompliance (NOT-OD-05-034)					X
	<ul> <li>Institute must promptly advise OLAW of any suspension of an animal activity by the IACUC (NOT-OD-05-034)</li> </ul>					X
•	Reports to U.S. Department of Agriculture (USDA) or Federal funding agency <sup>ix</sup>					
	Annual report to USDA contains required information including all					v
	exceptions/exemptions					X
	<ul> <li>Reporting mechanism to USDA is in place for IACUC-approved exceptions to the regulations and standards</li> </ul>					X
	<ul> <li>Reports are filed within 15 days for failures to adhere to timetable for correction of significant deficiencies</li> </ul>					X
	<ul> <li>Promptly reports suspensions of activities by the IACUC to USDA and any Federal funding agency</li> </ul>					X
•	Records (PHS Policy, IV.E.)					
	<ul> <li>IACUC meeting minutes and semiannual reports to the IO are maintained for 3 years</li> </ul>					X
	<ul> <li>Records of IACUC reviews of animal activities include all required information<sup>x</sup></li> </ul>					X
	<ul> <li>Records of IACUC reviews are maintained for 3 years after the completion of the study</li> </ul>					X
8. V	eterinary Care (See also next section - Veterinary Care)	<b>A</b> *	М	s	С	NA
•	An arrangement for veterinarian(s) with training or experience in lab animal medicine is in place including backup veterinary care <sup>xi</sup>	х				
•	Veterinary access to all animals is provided (Guide, p 14) [must]	X				
•	Direct or delegated authority is given to the veterinarian to oversee all aspects of					
	animal care and use ( <i>Guide</i> , <u>p 14</u> ) [must]	X				
•	Veterinarian provides consultation when pain and distress exceeds anticipated level in protocol ( $Guide, p 5$ ) [must]	X				
•	Veterinarian provides consultation when interventional control is not possible ( <i>Guide</i> , <u>p</u> <u>5</u> ) [must]	X				
•	If part time /consulting veterinarian, visits meet programmatic needs (Guide, p 14)	X				
	Regular communication occurs between veterinarian and IACUC ( <i>Guide</i> , <u>p 14</u> )	X				
•						_
•	Veterinarian(s) have experience and training in species used (Guide, p 15) [must]	X				

9. Pe	ersonnel Qualifications and Training  All personnel are adequately educated, trained, and/or qualified in basic principles of	<b>A</b> *	М	S	С	NA
•	laboratory animal science. Personnel included: [must]					
	Veterinary/other professional staff ( <i>Guide</i> , <u>p 15-16</u> )	X				
	o IACUC members ( <i>Guide</i> , p 17)	X				
	o Animal care personnel ( <i>Guide</i> , p 16)	X				
	<ul> <li>Research investigators, instructors, technicians, trainees, and students (Guide, pp 16-17)</li> </ul>	X				
•	Continuing education for program and research staff provided to ensure high quality care and reinforce training ( <i>Guide</i> , pp 16-17)	X				
•	Training is available prior to starting animal activity (Guide, p 17)	X				
•	Training is documented ( <i>Guide</i> , <u>p 15</u> )  Training program content includes: ( <i>Guide</i> , <u>p 17</u> )	X				
	Methods for reporting concerns ( <i>Guide</i> , <u>p 17</u> )	X				
	Humane practices of animal care (e.g., housing, husbandry, handling) xii	X				
	<ul> <li>Humane practices of animal use (e.g., research procedures, use of anesthesia, pre- and post-operative care, aseptic surgical techniques and euthanasia (Guide, p 17)xiii</li> </ul>	X				
	<ul> <li>Research/testing methods that minimize numbers necessary to obtain valid results (PHS Policy, <u>IV.A.1.q.</u>)</li> </ul>	X				
	<ul> <li>Research/testing methods that minimize animal pain or distress (PHS Policy, <u>IV.A.1.g.</u>)</li> </ul>	X				
	<ul> <li>Use of hazardous agents, including access to OSHA chemical hazard notices where applicable (Guide, p 20)</li> </ul>	X				
	o Animal care and use legislation ( <i>Guide</i> , <u>p 17</u> )				X	
	IACUC function ( <i>Guide</i> , <u>p 17</u> )	X				
	<ul> <li>Ethics of animal use and Three R's (Guide, p 17)</li> </ul>	X				
10.	Occupational Health and Safety of Personnel	$\mathbf{A}^*$	М	s	С	NA
•	Program is in place and is consistent with federal, state, and local regulations ( <i>Guide</i> , p 17) [must]	X				
•	Program covers <i>all</i> personnel who work in laboratory animal facilities ( <i>Guide</i> , <u>p 18</u> )	X				
•	Changing, washing, and showering facilities are available as appropriate ( <i>Guide</i> , <u>p 19</u> ) Hazardous facilities are separated from other areas and identified as limited access	X				
	(Guide, <u>p 19</u> )	X				
•	Personnel training is provided based on risk (e.g., zoonoses, hazards, personal hygiene, special precautions, animal allergies) ( <i>Guide</i> , p 20)	X				
	Derconal hydiene procedures are in place (e.g. work clothing, eating/drinking/smoking)					
•	Personal hygiene procedures are in place (e.g., work clothing, eating/drinking/smoking policies) ( <i>Guide</i> , p 20)	X				
•	policies) ( <i>Guide</i> , <u>p 20</u> )  Procedures for use, storage, and disposal of hazardous biologic, chemical, and physical agents are in place ( <i>Guide</i> , <u>p 21</u> )	X				
•	policies) ( <i>Guide</i> , <u>p 20</u> )  Procedures for use, storage, and disposal of hazardous biologic, chemical, and physical agents are in place ( <i>Guide</i> , <u>p 21</u> )  Personal Protective Equipment for the work area is appropriate and available ( <i>Guide</i> , <u>p 21</u> )	Х				
•	policies) ( <i>Guide</i> , <u>p 20</u> )  Procedures for use, storage, and disposal of hazardous biologic, chemical, and physical agents are in place ( <i>Guide</i> , <u>p 21</u> )  Personal Protective Equipment for the work area is appropriate and available ( <i>Guide</i> , <u>p 21</u> )  Program for medical evaluation and preventive medicine for personnel includes:	X				
•	policies) ( <i>Guide</i> , <u>p 20</u> )  Procedures for use, storage, and disposal of hazardous biologic, chemical, and physical agents are in place ( <i>Guide</i> , <u>p 21</u> )  Personal Protective Equipment for the work area is appropriate and available ( <i>Guide</i> , <u>p 21</u> )  Program for medical evaluation and preventive medicine for personnel includes:  Output  Ou	X				X
•	policies) (Guide, p 20)  Procedures for use, storage, and disposal of hazardous biologic, chemical, and physical agents are in place (Guide, p 21)  Personal Protective Equipment for the work area is appropriate and available (Guide, p 21)  Program for medical evaluation and preventive medicine for personnel includes:  • Pre-employment evaluation including health history (Guide, p 22)  • Immunizations as appropriate (e.g., rabies, tetanus) and tests as appropriate (Guide, p 22)  • Zoonosis surveillance as appropriate (e.g., Q-fever, tularemia, Hantavirus, plague)	X				X
•	policies) (Guide, p 20)  Procedures for use, storage, and disposal of hazardous biologic, chemical, and physical agents are in place (Guide, p 21)  Personal Protective Equipment for the work area is appropriate and available (Guide, p 21)  Program for medical evaluation and preventive medicine for personnel includes:  Output	X				

	o Considers confidentiality and other legal factors as required by federal, state and					v
	o If serum samples are collected, the purpose is consistent with federal and state laws (Guide, p 22) [must]					X
•	Waste anesthetic gases are scavenged (Guide, p 21)					X
•	Hearing protection is provided in high noise areas ( <i>Guide</i> , <u>p 22</u> )	X				
•	Respiratory protection is available when performing airborne particulate work ( <i>Guide</i> , p 22)	X				
•	Special precautions for personnel who work with nonhuman primates, their tissues or body fluids include:					
	Tuberculosis screening provided for all exposed personnel ( <i>Guide</i> , <u>p 23</u> )					X
	<ul> <li>Training and implementation of procedures for bites, scratches, or injuries associated with macaques (Guide, p 23)</li> </ul>					X
	<ul> <li>PPE is provided including gloves, arm protection, face masks, face shields, or goggles (Guide, p 21)</li> </ul>					X
	<ul> <li>Injuries associated with macaques are carefully evaluated and treatment implemented (Guide, p 23)</li> </ul>					X
•	Occupational safety and health of field studies is reviewed by OSH committee or office ( $Guide$ , $p$ 32)					X
11.	Personnel Security NEW	<b>A</b> *	М	s	С	N.A
•	Preventive measures in place include pre-employment screening, and physical and IT security ( <i>Guide</i> , <u>p 23</u> )	X				
12.	Investigating & Reporting Animal Welfare Concerns	$\mathbf{A}^*$	М	s	С	N.A
•	Methods for investigating and reporting animal welfare concerns are established (Guide, p 23) [must]				X	
•	Reported concerns and corrective actions are documented (Guide, p 24)				X	
•	Mechanisms for reporting concerns are posted in facility and at applicable website with instructions ( <i>Guide</i> , p 24)				X	
	Includes multiple contacts ( <i>Guide</i> , <u>p 24</u> )				X	
	<ul> <li>Includes anonymity, whistle blower policy, nondiscrimination and reprisal protection (Guide, p 24)</li> </ul>				X	

A = acceptable

**M** = minor deficiency

S = significant deficiency (is or may be a threat to animal health or safety)
C = change in program (PHS Policy <u>IV.A.1.a.-i.</u>) (include in semiannual report to IO and in annual report to OLAW)

NA = not applicable

### NOTES:

## **Veterinary Care**

Date: 11/6/2019

1.	Clinical Care and Management 🕬	$\mathbf{A}^*$	М	S	С	NA
	<ul> <li>Veterinary program offers high quality of care and ethical standards (Guide, p 105)</li> <li>[must]</li> </ul>	X				
	<ul> <li>Veterinarian provides guidance to all personnel to ensure appropriate husbandry, handling, treatment, anesthesia, analgesia, and euthanasia (Guide, p 106)</li> </ul>	X				
	• Veterinarian provides oversight to surgery and perioperative care (Guide, p 106)					X
	Veterinary care program is appropriate for program requirements (Guide, pp 113-114)	X				
	<ul> <li>Veterinarian(s) is familiar with species and use of animals and has access to medical and experimental treatment records (Guide, p 114)</li> </ul>	X				
	• Procedures to triage and prioritize incident reports are in place (Guide, p 114)					X

	Procedures are in place to address:					
•	Procedures are in place to address:  o Problems with experiments to determine course of treatment in consultation with investigator(Guide, p 114)	X				
	<ul> <li>Recurrent or significant health problems with the IACUC and documentation of treatments and outcomes (Guide, p 114)</li> </ul>					X
	<ul> <li>Veterinary review and oversight of medical and animal use records (Guide, p 115)</li> </ul>	X				
•	Procedures established for timely reporting of animal injury, illness, or disease ( <i>Guide</i> , p 114) [must]	X				
•	Procedures established for veterinary assessment, treatment, or euthanasia ( <i>Guide</i> , <u>p</u> <u>114</u> ) [must]	X				
•	Veterinarian is authorized to treat, relieve pain, and/or euthanize ( <i>Guide</i> , <u>p 114</u> )  [must]	X				
2. A	nimal Procurement and Transportation/Preventive Medicine	<b>A</b> *	М	S	С	NA
	Procedures for lawful animal procurement are in place (Guide, p 106) [must]	X				
	Sufficient facilities and expertise are confirmed prior to procurement (Guide, p 106)	X				
•	Procurement is linked to IACUC review and approval (Guide, p 106)	X				
•	Random source dogs and cats are inspected for identification (Guide, p 106)					X
•	Population status of wildlife species is considered prior to procurement (Guide, p 106)	X				
•	Appropriate records are maintained on animal acquisition (Guide, p 106)	X				
•	Animal vendors are evaluated to meet program needs and quality (Guide, p 106)	X				
•	Breeding colonies are based on need and managed to minimize numbers ( $Guide$ , $p$ $107$ )	X				
•	Procedures for compliance with animal transportation regulations, including international requirements, are in place ( <i>Guide</i> , <u>p 107</u> ) [must]	X				
•	Transportation is planned to ensure safety, security and minimize risk ( <i>Guide</i> , <u>p 107</u> ) Movement of animals is planned to minimize transit time and deliveries are planned to ensure receiving personnel are available ( <i>Guide</i> , <u>pp 107-108</u> )	X				
•	Appropriate loading and unloading facilities are available (Guide, p 109)	X				
•	Environment at receiving site is appropriate (Guide, p 109)	X				
•	Policies in place on separation by species, source, and health status ( <i>Guide</i> , <u>pp 109</u> , <u>111-112</u> )	X				
•	Procedures in place for quarantine to include zoonoses prevention (Guide, p 110)					X
•	Quarantined animals from different shipments are handled separately or physically separated ( $Guide$ , $p$ 110)	X				
•	Procedures in place for stabilization/acclimation (Guide, pp 110-111)	X				
•	Policies in place for isolation of sick animals (Guide, p 112)	X				
•	Program is in place for surveillance, diagnosis, treatment and control of disease to include daily observation ( $Guide$ , $p$ 112)	X				
•	Diagnostic resources are available for preventive health program (Guide, p 112)	X				
3. S	urgery	<b>A</b> *	М	S	С	NA
•	Surgical outcomes are assessed and corrective changes instituted (Guide, p 115)					X
•	Researchers have appropriate training to ensure good technique ( <i>Guide</i> , <u>p 115</u> ) [must]					X
•	Pre-surgical plans are developed and include veterinary input (e.g., location, supplies, anesthetic and analgesic use, peri-operative care, recordkeeping) ( <i>Guide</i> , p 116)					X
•	Aseptic surgery is conducted in dedicated facilities or spaces, unless exception justified and IACUC approved ( <i>Guide</i> , p 116)					X
•	Surgical procedures including laparoscopic procedures are categorized as major or minor ( <i>Guide</i> , pp 117-118)					X
•	For nonsurvival surgery, the site is clipped, gloves are worn and instruments and area are clean ( <i>Guide</i> , p 118)					X
	7777 0 1 10 11 1					

						X
_	Aseptic technique is followed for survival surgical procedures ( <i>Guide</i> , pp 118-119)     Effective procedures for starilizing instruments and manifesting expiration dates on					
	<ul> <li>Effective procedures for sterilizing instruments and monitoring expiration dates on sterile packs are in place (Guide, p 119)</li> </ul>					X
	<ul> <li>Procedures for monitoring surgical anesthesia and analgesia are in place (Guide, p 119)</li> </ul>					X
	• For aquatic species, skin surfaces are kept moist during surgical procedures ( <i>Guide</i> , <u>p</u> 119)					X
	<ul> <li>Post-operative monitoring and care are provided by trained personnel and documented (e.g., thermoregulation, physiologic function, analgesia, infection, removal of skin closures) (Guide, pp 119-120)</li> </ul>					X
	Pain, Distress, Anesthesia and Analgesia	<b>A</b> *	М	s	С	NA
	<ul> <li>Guidelines for assessment and categorization of pain, distress and animal wellbeing are provided during training (Guide, p 121)</li> </ul>	X				
	<ul> <li>Selection of analgesics and anesthetics is based on professional veterinary judgment (Guide, p 121) MS-222, Rapid chilling</li> </ul>	X				
	<ul> <li>Painful procedures are monitored to ensure appropriate analgesic management (Guide, p 122)</li> </ul>	X				
	<ul> <li>Nonpharmacologic control of pain is considered as an element of postprocedural care (Guide, p 122)</li> </ul>					Х
	<ul> <li>Procedures are in place to assure antinoception before surgery begins (Guide, p 122)</li> <li>[must]</li> </ul>					X
	<ul> <li>Guidelines for selection and use of analgesics and anesthetics are in place and regularly reviewed and updated (Guide, p 122)</li> </ul>					X
	<ul> <li>Special precautions for the use of paralytics are in place to ensure anesthesiaxiv (Guide, p 123)</li> </ul>					X
	Euthanasia	<b>A</b> *	М	s	С	N.A
	<ul> <li>Methods are consistent with AVMA Guidelines on Euthanasia unless approved by the IACUC (Guide, p 123)</li> </ul>	X				
	Standardized methods are developed and approved by the veterinarian and IACUC that avoid distress and consider animal age and species (Guide, pp 123-124)	X				
	<ul> <li>Training is provided on appropriate methods for each species and considers psychological stress to personnel (Guide, p 124)</li> </ul>	X				
	<ul> <li>Procedures and training are in place to ensure death is confirmed (Guide, p 124)</li> <li>[must]</li> </ul>	X				
	Drug Storage and Control NEW	<b>A</b> *	М	s	С	N.A
	<ul> <li>Program complies with federal regulations for human and veterinary drugs(Guide, p 115) [must]</li> </ul>	X				
	<ul> <li>Drug records and storage procedures are reviewed during facility inspections (Guide, p 115)</li> </ul>	X				
	Procedures are in place to ensure analgesics and anesthetics are used within expiration date ( <i>Guide</i> , p 122) [must]	X				
	<ul> <li>Anesthetics and analgesics are acquired, stored, and their use and disposal are recorded legally and safely (Guide, p 122)</li> </ul>	X				
	A = accontable					

<sup>\*</sup> A = acceptable

### NOTES:

M = minor deficiency
 S = significant deficiency (is or may be a threat to animal health or safety)
 C = change in program (PHS Policy <u>IV.A.1.a.-i.</u>) (include in semiannual report to IO and in annual report to OLAW)

NA = not applicable

### **II. Semiannual Facility Inspection Report**

Date: 11/6/2019

Members in Attendance: Exemption 6Exemption 6Exemption 6 Leslie Jarrell (via facetime), Exemption 6 **Deficiency Deficiency and** Responsible **Correction Schedule** Date Category\*  $\checkmark$ Plan for Correction and Interim Status Location **Partv** Complete Several tanks with high density of Flat Head Minnows-thin fish М Rm 159 Split density of tanks 11/20/2019 into more tanks Μ Rm 159 1 Large Single Housed Blue Gill Fish-multiple house Disposed 11/20/2019 Μ Rm 159 Lab coat hanging on Fish Rack-remove lab coat and store in Removed Lab coat 11/7/2019 another room М Rm 159 Rusty Razor Blade-dispose of razor blade Disposed of blade 11/7/2019 М Rm 159 Wood in the room- replace with plastic Removed wood 11/19/2019 М Rm 159 Particle board clipboards-replace with plastic clipboards Replaced with plastic 11/12/2019 clipboards М Rm 160 Several tanks with high density of Flat Head Minnows-thin fish Split density of tanks into more tanks 11/20/2019 М Rm 160 Oxygen Tank needs to be more secured to rack Moved O2 tanks to 11/7/2019 storage container М Rm 160 Rusty Razor Blade-dispose of razor blade Disposed of blade 11/7/2019 Μ Rm 162 Lab coat hanging on Fish Rack-remove lab coat and store in Moved lab coats 11/7/2019 another room Μ Rm 162 Broken 5G Tank-remove broken tank 11/7/2019 Disposed of Tank М Rm 163 Freezers, paint is peeling off and rusty-replace freezers New Freezers on order 01/21/2020 М Rm 163 Storage of unbagged carcasses with food-bag carcasses and Disposed of carcasses 11/8/2019 store food in another freezer М Rm 166 Electric junction box setting on rack with water pump-attach Facilities will re-wire 12/10/2019 electric junction box to wall М Rm 166 Wood in room-replace with plastic Removed wood 11/19/2019 М Rm 167 Wood in room-replace with plastic Removed wood 11/19/2019 Replaced with plastic 11/12/2019 М Rm 167 Particle board clipboards-replace with plastic clipboards

clipboards

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М	Rm 167	Bleach container-do not keep in room	Moved bleach to another room	11/7/2019
М	Rm 167	Broken Trash can-replace with another trash can	Disposed of broken trash can	11/7/2019
М	Rm 167	Cardboard box on floor-remove cardboard from the room	Removed Cardboard from the room	11/19/2019
М	Rm 167	Items on the floor-remove items as they are trip hazards	Items were moved	11/7/2019
М	Rm 167	Drain covers in sink- store these closer to the drains	Moved Drain covers close to sink	11/7/2019
М	Rm 167	GFCI Protected Outlets-make sure these are really GFI	Tested, they are GFI	11/19/2019
М	Rm 168	Stir plate sitting on wood-remove wood, replace with plastic	Removed wood	11/19/2019
М	Rm 168	Furniture mover is wood, remove mover from this room	Removed furniture mover	11/12/2019
М	Rm 168	Particle board clipboards-replace with plastic clipboards	Replaced with plastic clipboard	11/12/2019
М	Rm 168	Electric junction box setting on rack with water pump-attach electric junction box to wall	Facilities will move box	12/10/2019
М	Rm 169	Cardboard on top of racks-remove and replace with plastic	Removed cardboard	11/19/2019
М		UV light, unit states failure-fix sensor	Replaced sensor	12/10/2019
М		Light levels in room with Albino frogs-need to detect levels as Albino frogs are more sensitive to light	Facilities will check light levels	12/10/2019
М		Body conditioning of Zebrafish-learn how to score on body condition	File sent from RTP	11/7/2019
М		Liquid chemicals in rooms on high shelves-move liquid chemicals to lower shelf	Moved to lower shelf	11/7/2019
М		Metal chair with wooden top-remove chair from room	Removed chair from the room	11/7/2019

<sup>\*</sup> **A** = acceptable

**M** = minor deficiency

S = significant deficiency (is or may be a threat to animal health or safety)
C = change in program (PHS Policy IV.A.1.a.-i.) (include in semiannual report to IO and in annual report to OLAW)
NA = not applicable

√ Check if repeat deficiency

### III. Endnotes

<sup>i</sup> The PHS Policy requires that Assured institutions comply with the regulations (9 CFR, Subchapter A) issued by the U.S. Department of Agriculture (USDA) under the Animal Welfare Act, as applicable. The endnotes below are specific USDA regulatory requirements that differ from or are in addition to the PHS Policy. This list is not intended to be all inclusive. For additional information please refer to 9 CFR Subchapter A - Animal Welfare.

- 2.31(b)(2) "The Committee shall be composed of a Chairman and at least two additional members;... at least one shall not be affiliated in any way with the facility...such person will provide representation for general community interests in the proper care and treatment of animals." [PHS policy requires 5 members]
- iii 2.32(c)(4) "...No facility employee, Committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulation or standards under the Act." [USDA requirement additional to PHS Policy]
- iv 2.31(d)(5) "...shall conduct continuing reviews of activities...not less than annually." [PHS Policy requires a complete new review every 3 years utilizing all the criteria for initial review]
- $^{v}$  2.31(d)(1)(x) "...no animal will be used in more than one major operative procedure from which it is allowed to recover unless...(it is) justified for scientific reasons...(or is) required as routine veterinary procedure...or other special circumstances as determined by the Administrator on an individual basis." [this last point is an additional USDA justification for multiple survival surgeries]
- vi 2.36 "...each reporting facility shall submit an annual report to the APHIS, AC sector supervisor for the State where the facility is located on or before December 1 of each calendar year." [The USDA annual report has a list of requirements which differ from PHS annual report]
- vii 2.36(b)(3) "...exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the IACUC. A summary of all such exceptions must be attached to the facility's annual report." [Refers to USDA annual report]
- viii 2.31(c)(3) "...Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected shall be reported in writing within 15 business days by the IACUC, through the institutional official, to APHIS and any Federal agency funding that activity." [PHS Policy requires prompt reporting to OPRR of serious or continuing noncompliance with the PHS Policy or serious deviations from the provisions of the *Guide*]
- <sup>ix</sup> 2.36 "...each reporting facility shall submit an annual report to the APHIS, AC sector supervisor for the State where the facility is located on or before December 1 of each calendar year." [The USDA annual report has a list of requirements which differ from PHS annual report]
- x In addition to PHS requirements for IACUC review/application for funding, USDA regulations require: 2.31(d)(1)(ii) "The principal investigator (PI) consider alternatives to procedures that cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources...used to determine that alternatives were not available."
  - 2.31(d)(1)(iii) "The PI has provided written assurance that the activities do not unnecessarily duplicate previous experiments."
  - 2.31(d)(1)(iv) "Procedures that may cause more than momentary or slight pain or distress to the animals will:
    - involve in their planning, consultation with the attending veterinarian or his or her designee; [PHS Policy does not specify veterinary consultation]
    - not include paralytics without the use of anesthesia;"

ii Part 2 Subpart C - Research Facilities

- 2.31(d)(1)(x) "No animal will be used in more than one major operative procedure from which it is allowed to recover, unless justified for scientific reasons by the principal investigator, in writing..."
- xi 2.33(a)(1) "In the case of a part-time attending veterinarian or consultant arrangements, the formal arrangements shall include a written program of veterinary care and regularly scheduled visits to the research facility." [USDA requirement additional]
- xii 2.32(c) "Humane methods of animal maintenance and experimentation, including the basic needs of each species, proper handling and care for the various species of animals used by the facility, proper pre-procedural and post-procedural care of animals, and aseptic surgical methods and procedures."
- xiii 2.32(c) additional specifications include:
- "proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility"
- "methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility..."
- "utilization of services (e.g., National Agricultural Library, National Library of Medicine) to provide information on appropriate animal care and use, alternatives to the use of live animals in research , that could prevent unintended and unnecessary duplication of research involving animals, and regarding the intent and requirements of the Act." [USDA training specifications are more detailed than PHS Policy].
- $^{xiv}$  2.31(d)(iv)(C) "Procedures that may cause more than momentary or slight pain or distress to the animals will...not include the use of paralytics without anesthesia."

### **Semiannual Program Review and Facility Inspection Checklist**

#### About the checklist

The Semiannual Program Review and Facility Inspection Checklist is provided to assist institutions in conducting their semiannual reviews of programs and facilities for the care and use of animals. The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy), section IV.B.1.-2., requires the Institutional Animal Care and Use Committee (IACUC) to review the institution's program for humane care and use of animals and inspect all of the institution's animal facilities at least once every 6 months using the *Guide* for the Care and Use of Laboratory Animals: Eighth Edition (Guide) as a basis for evaluation.

#### How to use the checklist

This checklist is a tool to assist IACUCs in conducting thorough semiannual reviews. IACUCs are not required to use this checklist but are encouraged to amend it as necessary to reflect institutional programs and needs, or to develop their own checklist. If the checklist is modified, periodic review of the checklist is recommended to ensure relevant topics are considered as the animal care and use program changes.

The checklist covers the major topics of the *Guide* and the requirements of the PHS Policy. The checklist does not replace the *Guide*, but should be utilized in conjunction with the *Guide*. The *Guide* provides the standards, recommendations, and descriptions of desired outcomes necessary to evaluate and inspect an animal care and use program. Relevant references for the *Guide* and the PHS Policy are noted. Endnotes are included to reference specific U.S. Department of Agriculture (USDA) regulatory requirements that differ from the PHS Policy. Topics that are new to this version of the checklist or identified as a "must" in the *Guide* are highlighted. A column to identify changes that have occurred in the institution's program for animal care and use (PHS Policy IV.A.1.a.-i.) since the last review is also a new feature.

The checklist consists of the following sections:

- I. Semiannual Program Review Checklist
  - Institutional Policies and Responsibilities
  - Veterinary Care
- II. Semiannual Facility Inspection Checklist
  - Terrestrial Animal Housing and Support Areas
  - Aquatic Animal Housing and Support Areas
  - Cagewash
  - Special Facilities: Aseptic Surgery
  - Special Facilities: Procedure Areas, Non-survival Surgeries, Laboratories, Rodent Surgeries, Imaging, Whole Body Irradiation, Hazardous Agent Containment, Behavioral Studies
- III. Semiannual Program Review and Facility Inspection Report
- IV. Endnotes

It is recommended that the Program Review section be completed during an IACUC meeting. Because physical aspects of a program require visual observation to evaluate, it is recommended that the Facility Inspection section be completed during an inspection of the facilities, including satellite facilities.

A table is provided, "Semiannual Program Review and Facility Inspection Report," as a format for the IACUC to organize and track information regarding deficiencies, and plans and schedules for correction. IACUCs may choose to attach the table to the Semiannual Report to the Institutional Official.

### **Questions or comments?**

Suggestions or comments about this checklist should be e-mailed to: <a href="mailto:olawdpe@mail.nih.gov">olawdpe@mail.nih.gov</a>.

# I. Semiannual Program Review Checklist i

Institutional Policies and Responsibilities
Exemption 6Exemption 6Exemption 6Exemption 6

Date: 12/12/2019

. Animal Care and Use Program 👯	$\mathbf{A}^*$	M	S	C	NA
<ul> <li>Responsibility for animal well-being is assumed by all members of the program (Guide p 1) must</li> </ul>	X				
<ul> <li>IO has authority to allocate needed resources (Guide, p 13)</li> </ul>	X				
<ul> <li>Resources necessary to manage program of veterinary care are provided (Guide, p 14)</li> <li>[must]</li> </ul>	X				
<ul> <li>Sufficient resources are available to manage the program, including training of personnel in accord with regulations and the Guide (Guide, pp 11, 15)</li> </ul>	X				
• Program needs are regularly communicated to IO by AV and/or IACUC (Guide, p 13)	X				
<ul> <li>Responsibilities for daily animal care and facility management are assigned to specific individual(s) when a full-time veterinarian is not available on site (Guide, p 14) [must]</li> </ul>	X				
<ul> <li>Inter-institutional collaborations are described in formal written agreements (Guide, p 15) QA Plans</li> </ul>	X				
<ul> <li>Written agreements address responsibilities, animal ownership, and IACUC oversight (Guide, p 15) MOAs</li> </ul>	X				
. Disaster Planning and Emergency Preparedness 👫	$\mathbf{A}^*$	М	S	С	NA
<ul> <li>Disaster plans for each facility to include satellite locations are in place (Guide, p 35, p 75) [must]</li> </ul>	X				
<ul> <li>Plans include provisions for euthanasia (Guide, p 35) [must]</li> </ul>	X				
<ul> <li>Plans include triage plans to meet institutional and investigators' needs (Guide, p 35)</li> </ul>		X		X	
<ul> <li>Plans define actions to prevent animal injury or death due to HVAC or other failures (Guide, p 35)</li> </ul>	X				
Plans describe preservation of critical or irreplaceable animals (Guide, p 35)	X				
Plans include essential personnel and their training (Guide, p 35)	X				
<ul> <li>Animal facility plans are approved by the institution and incorporated into overall response plan (Guide, p 35)</li> </ul>	X				
<ul> <li>Law enforcement and emergency personnel are provided a copy and integration with overall plan is in place (Guide, p 35)</li> </ul>	X				
. IACUC NEW	<b>A</b> *	М	s	С	NA
<ul> <li>Meets as necessary to fulfill responsibilities (Guide, p 25) [must]</li> </ul>	X				
<ul> <li>IACUC Members named in protocols or with conflicts recuse themselves from protocol decisions (Guide, p 26) [must]</li> </ul>	X				
• Continuing IACUC oversight after initial protocol approval is in place (Guide, p 33)	X				

	•	IACUC evaluates the effectiveness of training programs ( <i>Guide</i> , <u>p 15</u> )	X				
ŀ.	ΙA	CUC Protocol Review - Special Considerations	<b>A</b> *	М	s	С	NA
	•	Humane endpoints are established for studies that involve tumor models, infectious diseases, vaccine challenge, pain modeling, trauma, production of monoclonal antibodies, assessment of toxicologic effects, organ or system failure, and models of cardiovascular shock ( <i>Guide</i> , <u>p 27</u> )	X				
	•						X
	•	For genetically modified animals, enhanced monitoring and reporting is in place ( <i>Guide</i> , <u>p 28</u> )					X
	•	Restraint devices are justified in the animal use protocols (Guide, p 29) [must]					X
	•	Alternatives to physical restraint are considered (Guide, p 29)					X
	•	Period of restraint is the minimum to meet scientific objectives (Guide, p 29)					X
	•	Training of animals to adapt to restraint is provided (Guide, p 29)					X
	•	Animals that fail to adapt are removed from study (Guide, p 29)					X
	•	Appropriate observation intervals of restrained animals are provided (Guide, p 29)					X
	•	Veterinary care is provided if lesions or illness result from restraint ( <i>Guide</i> , <u>p 30</u> )  [must]					X
	•	Explanations of purpose and duration of restraint are provided to study personnel ( $Guide$ , $p$ 30)					X
	•	Multiple surgical procedures on a single animal are justified and outcomes evaluated (Guide, p 30)					X
	•	Major versus minor surgical procedures are evaluated on a case-by-case basis ( <i>Guide</i> , p 30)					X
	•	Multiple survival procedure justifications in non-regulated species conform to regulated species standards ( <i>Guide</i> , p 30)					X
	•	Animals on food/fluid restriction are monitored to ensure nutritional needs are met (Guide, p 31)					X
	•	Body weights for food/fluid restricted animals are recorded at least weekly (Guide, $\underline{p}$ 31)					X
	•	Daily written records are maintained for food/fluid restricted animals (Guide, p 31)					X
	•	Pharmaceutical grade chemicals are used , when available, for animal-related procedures ( <i>Guide</i> , <u>p 31</u> )	X				
	•	Non-pharmaceutical grade chemicals are described, justified, and approved by IACUC (Guide, $p$ 31)	X				
	•	Investigators conducting field studies know zoonotic diseases, safety issues, laws and regulations applicable in study area ( $Guide$ , $p$ 32)	X				
	•	Disposition plans are considered for species removed from the wild (Guide, p 32)	X				
	•	Toe-clipping only used when no alternative, performed aseptically and with pain relief ( $Guide$ , $p$ 75)					X

5. IAC	UC Membership and Functions	$\mathbf{A}^*$	М	S	С	NA
• I/	ACUC is comprised of at least 5 members, appointed by CEO (PHS Policy, <u>IV.A.3.</u> )	X				
• M a	lembers include a veterinarian, a scientist, a nonscientist, and a nonaffiliated non-lab nimal user ( <i>Guide</i> , <u>p 24</u> ) <sup>ii</sup>	X				
a	ACUC authority and resources for oversight and evaluation of institution's program re provided ( <i>Guide</i> , <u>p 14</u> )	X				
	ACUC conducts semiannual evaluations of institutional animal care and use program PHS Policy, <u>IV.B.</u> )	X				
• C	onducts semiannual inspections of institutional animal facilities (PHS Policy, <u>IV.B.</u> )	X				
• I/	ACUC organizationally reports to the Institutional Official (PHS Policy, <u>IV.A.1.b.</u> )	X				
	lethods for reporting and investigating animal welfare concerns are in place ( <i>Guide</i> , <u>p</u> 3) [must]	X				
Р	eviews and investigates concerns about animal care and use at institution <sup>iii</sup> (PHS olicy, IV.B.)	X				
(1	rocedures are in place for review, approval, and suspension of animal activities <sup>iv</sup> PHS Policy, <u>IV.B.</u> )	X				
a	rocedures are in place for review and approval of significant changes to approved ctivities (PHS Policy, IV.B.)	X				
re	olicies are in place for special procedures (e.g., genetically modified animals, estraint, multiple survival surgery, food and fluid regulation, field investigations, gricultural animals) ( <i>Guide</i> , <u>p 27-32</u> ) QA Plans	X				
• R	equests for exemptions from major survival surgical procedure restrictions are made USDA/APHIS* ( <i>Guide</i> , <u>p 30</u> ) [must]					X
5. IACI	UC Training №	$\mathbf{A}^*$	М	S	С	N/
	Il IACUC members should receive:					
0	Formal orientation to institution's program (Guide, p 17)	X				
0	Training on legislation, regulations, guidelines, and policies ( <i>Guide</i> , p 17)	X				
0		X				
0	Training on how to review protocols as well as evaluate the program (Guide, p 17)	X				
0	Ongoing training/education ( <i>Guide</i> , <u>p 17</u> )	X				
	UC Records and Reporting Requirements <sup>vi</sup>	<b>A</b> *	M	s	С	N/
• 5	emiannual report to the IO (PHS Policy, <u>IV.B.</u> )	v				
0		X				
0	To de de la companya de la Colonia	X				
0		-				X

Distinguishes significant from minor deficiencies	X				
<ul> <li>Includes a plan and schedule for correction for each deficiency identified viii</li> </ul>	X				
Reports to OLAW (PHS Policy, <u>IV.F.</u> )					
<ul> <li>Annual report to OLAW documents program changes, dates of the semiannual program reviews and facility inspections and includes any minority views</li> </ul>					2
o Promptly advises OLAW of serious/ongoing <i>Guide</i> deviations or PHS Policy					ľ
noncompliance (NOT-OD-05-034)					2
<ul> <li>Institute must promptly advise OLAW of any suspension of an animal activity by the IACUC (NOT-OD-05-034)</li> </ul>					2
<ul> <li>Reports to U.S. Department of Agriculture (USDA) or Federal funding agency<sup>ix</sup></li> </ul>					
<ul> <li>Annual report to USDA contains required information including all exceptions/exemptions</li> </ul>					2
<ul> <li>Reporting mechanism to USDA is in place for IACUC-approved exceptions to the regulations and standards</li> </ul>					2
<ul> <li>Reports are filed within 15 days for failures to adhere to timetable for correction significant deficiencies</li> </ul>					2
<ul> <li>Promptly reports suspensions of activities by the IACUC to USDA and any Federa funding agency</li> </ul>	I				2
Records (PHS Policy, <u>IV.E.</u> )					
<ul> <li>IACUC meeting minutes and semiannual reports to the IO are maintained for 3 years</li> </ul>	X				
,	X				
<ul> <li>Records of IACUC reviews of animal activities include all required information<sup>x</sup></li> </ul>	^				
<ul> <li>Records of IACUC reviews of animal activities include all required information<sup>x</sup></li> <li>Records of IACUC reviews are maintained for 3 years after the completion of the study</li> </ul>					
<ul> <li>Records of IACUC reviews are maintained for 3 years after the completion of the study</li> </ul>	X	м	S	С	N
<ul> <li>Records of IACUC reviews are maintained for 3 years after the completion of the study</li> </ul>	X A*	М	S	С	N
<ul> <li>Records of IACUC reviews are maintained for 3 years after the completion of the study</li> <li>Veterinary Care (See also next section - Veterinary Care)</li> <li>An arrangement for veterinarian(s) with training or experience in lab animal medicin is in place including backup veterinary carexi</li> </ul>	<b>X A</b> *	M	S	С	•
<ul> <li>Records of IACUC reviews are maintained for 3 years after the completion of the study</li> <li>Veterinary Care (See also next section - Veterinary Care)</li> <li>An arrangement for veterinarian(s) with training or experience in lab animal medicin is in place including backup veterinary carexi</li> </ul>	<b>X A* e X</b>	M	S	C	N
<ul> <li>Records of IACUC reviews are maintained for 3 years after the completion of the study</li> <li>Veterinary Care (See also next section - Veterinary Care)</li> <li>An arrangement for veterinarian(s) with training or experience in lab animal medicin is in place including backup veterinary carexi</li> <li>Veterinary access to all animals is provided (Guide, p 14) [must]</li> <li>Direct or delegated authority is given to the veterinarian to oversee all aspects of animal care and use (Guide, p 14) [must]</li> <li>Veterinarian provides consultation when pain and distress exceeds anticipated level in protocol (Guide, p 5) [must]</li> </ul>	A* e X X X	M	S	С	<b>N</b>
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<ul> <li>Records of IACUC reviews are maintained for 3 years after the completion of the study</li> <li>Veterinary Care (See also next section - Veterinary Care)</li> <li>An arrangement for veterinarian(s) with training or experience in lab animal medicin is in place including backup veterinary carexi</li> <li>Veterinary access to all animals is provided (Guide, p 14) [must]</li> <li>Direct or delegated authority is given to the veterinarian to oversee all aspects of animal care and use (Guide, p 14) [must]</li> <li>Veterinarian provides consultation when pain and distress exceeds anticipated level in protocol (Guide, p 5) [must]</li> <li>Veterinarian provides consultation when interventional control is not possible (Guide 5) [must]</li> <li>If part time /consulting veterinarian, visits meet programmatic needs (Guide, p 14)</li> </ul>	A*  E X  X  X  X  X  X  X  X  X  X  X	M	S	С	
<ul> <li>Records of IACUC reviews are maintained for 3 years after the completion of the study</li> <li>Veterinary Care (See also next section - Veterinary Care)</li> <li>An arrangement for veterinarian(s) with training or experience in lab animal medicin is in place including backup veterinary carexi</li> <li>Veterinary access to all animals is provided (Guide, p 14) [must]</li> <li>Direct or delegated authority is given to the veterinarian to oversee all aspects of animal care and use (Guide, p 14) [must]</li> <li>Veterinarian provides consultation when pain and distress exceeds anticipated level in protocol (Guide, p 5) [must]</li> <li>Veterinarian provides consultation when interventional control is not possible (Guide 5) [must]</li> <li>If part time /consulting veterinarian, visits meet programmatic needs (Guide, p 14)</li> <li>Regular communication occurs between veterinarian and IACUC (Guide, p 14)</li> </ul>	A*  E X  X  X  X  X  X  X  X  X  X  X	M	S	C	
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	laboratory animal science. Personnel included: [must]					
	Veterinary/other professional staff ( <i>Guide</i> , <u>p 15-16</u> )	X				
	IACUC members (Guide, p 17)	X				
	Animal care personnel ( <i>Guide</i> , p 16)	X				
	<ul> <li>Research investigators, instructors, technicians, trainees, and students (Guide, pp 16-17)</li> </ul>	X				
•	Continuing education for program and research staff provided to ensure high quality care and reinforce training ( $Guide$ , $pp 16-17$ )	X				
•	Training is available prior to starting animal activity (Guide, p 17)	X				
•	Training is documented ( <i>Guide</i> , <u>p 15</u> )	X				
•	Training program content includes: ( <i>Guide</i> , <u>p 17</u> )			I	ı	
	<ul> <li>Methods for reporting concerns (Guide, p 17)</li> </ul>	X				
	<ul> <li>Humane practices of animal care (e.g., housing, husbandry, handling) xii</li> </ul>	X				
	<ul> <li>Humane practices of animal use (e.g., research procedures, use of anesthesia, pre- and post-operative care, aseptic surgical techniques and euthanasia (Guide, p 17)<sup>xiii</sup></li> </ul>	X				
	<ul> <li>Research/testing methods that minimize numbers necessary to obtain valid results (PHS Policy, <u>IV.A.1.q.</u>)</li> </ul>	X				
	<ul> <li>Research/testing methods that minimize animal pain or distress (PHS Policy, IV.A.1.g.)</li> </ul>	X				
	<ul> <li>Use of hazardous agents, including access to OSHA chemical hazard notices where applicable (Guide, p 20)</li> </ul>	X				
	<ul> <li>Animal care and use legislation (Guide, p 17)</li> </ul>	X				
	o IACUC function (Guide, p 17)	X				
	o Ethics of animal use and Three R's (Guide, p 17)	X				
10.	Occupational Health and Safety of Personnel	<b>A</b> *	М	s	С	NA
•	Program is in place and is consistent with federal, state, and local regulations ( <i>Guide</i> , p 17) [must]	X				
•	Program covers all personnel who work in laboratory animal facilities (Guide, p 18)	X				
•	Changing, washing, and showering facilities are available as appropriate (Guide, p 19)	X				
•	Hazardous facilities are separated from other areas and identified as limited access (Guide, p 19)	X				
•	Personnel training is provided based on risk (e.g., zoonoses, hazards, personal hygiene, special precautions, animal allergies) ( <i>Guide</i> , p 20)	X				
•	Personal hygiene procedures are in place (e.g., work clothing, eating/drinking/smoking policies) ( $Guide$ , $p$ 20)	<b>X</b>				
•	Procedures for use, storage, and disposal of hazardous biologic, chemical, and physical agents are in place ( $Guide$ , $p$ 21)	X				

<ul> <li>Personal Protective Equipment for the work area is appropriate and available (Guide, 21)</li> </ul>	X				
<ul> <li>Program for medical evaluation and preventive medicine for personnel includes:</li> </ul>					
<ul> <li>Pre-employment evaluation including health history (Guide, p 22)</li> </ul>					X
<ul> <li>Immunizations as appropriate (e.g., rabies, tetanus) and tests as appropriate (Guide, p 22)</li> </ul>	X				
<ul> <li>Zoonosis surveillance as appropriate (e.g., Q-fever, tularemia, Hantavirus, plague (Guide, p 23)</li> </ul>					X
<ul> <li>Procedures for reporting and treating injuries, including accidents, bites, allergies, etc. (Guide, p 23)</li> </ul>	X				
<ul> <li>Promotes early diagnosis of allergies including preexisting conditions (Guide, p 22</li> </ul>	)				X
<ul> <li>Considers confidentiality and other legal factors as required by federal, state and local regulations (Guide, p 22) [must]</li> </ul>					
<ul> <li>If serum samples are collected, the purpose is consistent with federal and state laws (Guide, p 22) [must]</li> </ul>					X
Waste anesthetic gases are scavenged (Guide, p 21)					X
<ul> <li>Hearing protection is provided in high noise areas (Guide, p 22)</li> </ul>	X				
<ul> <li>Respiratory protection is available when performing airborne particulate work (Guide, p 22)</li> </ul>	X				
<ul> <li>Special precautions for personnel who work with nonhuman primates, their tissues or body fluids include:</li> </ul>					
<ul> <li>Tuberculosis screening provided for all exposed personnel (Guide, p 23)</li> </ul>					X
<ul> <li>Training and implementation of procedures for bites, scratches, or injuries associated with macaques (Guide, p 23)</li> </ul>					X
<ul> <li>PPE is provided including gloves, arm protection, face masks, face shields, or goggles (Guide, p 21)</li> </ul>					X
<ul> <li>Injuries associated with macaques are carefully evaluated and treatment implemented (Guide, p 23)</li> </ul>					X
<ul> <li>Occupational safety and health of field studies is reviewed by OSH committee or office (Guide, p 32)</li> </ul>					X
11. Personnel Security 👯	<b>A</b> *	М	s	С	N.A
<ul> <li>Preventive measures in place include pre-employment screening, and physical and IT security (Guide, p 23)</li> </ul>	X				
12. Investigating & Reporting Animal Welfare Concerns 🕬	<b>A</b> *	М	s	С	N.A
<ul> <li>Methods for investigating and reporting animal welfare concerns are established (Guide, p 23) [must]</li> </ul>	X				
<ul> <li>Reported concerns and corrective actions are documented (Guide, p 24)</li> </ul>	X				
<ul> <li>Mechanisms for reporting concerns are posted in facility and at applicable website with instructions (Guide, p 24) Website is currently down.</li> </ul>	h			X	

<ul> <li>Includes multiple contacts</li> </ul>	s (Guide, <u>p 24</u> )	
<ul> <li>Includes anonymity, whis protection (Guide, p 24)</li> </ul>	tle blower policy, nondiscrimination and reprisal	,

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NA = not applicable

### NOTES:

# **Veterinary Care**

Date: 12/12/2019

. Clinical Care and Management 👯	$\mathbf{A}^*$	М	S	С	N
<ul> <li>Veterinary program offers high quality of care and ethical standards (Guide, p 105)</li> <li>must</li> </ul>	X				
<ul> <li>Veterinarian provides guidance to all personnel to ensure appropriate husbandry, handling, treatment, anesthesia, analgesia, and euthanasia (Guide, p 106)</li> </ul>	X				
• Veterinarian provides oversight to surgery and perioperative care ( <i>Guide</i> , <u>p 106</u> )					)
<ul> <li>Veterinary care program is appropriate for program requirements (<i>Guide</i>, pp 113-114)</li> <li>Veterinarian(s) is familiar with species and use of animals and has access to medical</li> </ul>	X				
and experimental treatment records ( <i>Guide</i> , <u>p 114</u> )	X				
<ul> <li>Procedures to triage and prioritize incident reports are in place (Guide, p 114)</li> <li>Procedures are in place to address:</li> </ul>	X				
<ul> <li>Problems with experiments to determine course of treatment in consultation with investigator(Guide, p 114)</li> </ul>	X				
<ul> <li>Recurrent or significant health problems with the IACUC and documentation of treatments and outcomes (Guide, p 114)</li> </ul>	X				
<ul> <li>Veterinary review and oversight of medical and animal use records (Guide, p 115)</li> </ul>					2
<ul> <li>Procedures established for timely reporting of animal injury, illness, or disease (Guide, p 114) [must]</li> </ul>				X	
<ul> <li>Procedures established for veterinary assessment, treatment, or euthanasia (Guide, p 114) [must]</li> </ul>				X	
<ul> <li>Veterinarian is authorized to treat, relieve pain, and/or euthanize (Guide, p 114)</li> <li>must</li> </ul>	X				
Animal Procurement and Transportation/Preventive Medicine	<b>A</b> *	М	s	С	r
Procedures for lawful animal procurement are in place (Guide, p 106) [must]	X				
Sufficient facilities and expertise are confirmed prior to procurement (Guide, p 106)	X				L
Procurement is linked to IACUC review and approval (Guide, p 106)	X				L
Random source dogs and cats are inspected for identification (Guide, p 106)					2
• Population status of wildlife species is considered prior to procurement ( <i>Guide</i> , <u>p 106</u> )	X				
Appropriate records are maintained on animal acquisition (Guide, p 106)	X				L
Animal vendors are evaluated to meet program needs and quality (Guide, p 106)  Paradia and program and the minimized and					
<ul> <li>Breeding colonies are based on need and managed to minimize numbers (Guide, p 107)</li> </ul>	X				
<ul> <li>Procedures for compliance with animal transportation regulations, including international requirements, are in place (Guide, p 107) [must]</li> </ul>	X				

<ul> <li>Guidelines for assessment and categorization of pain, distress and animal wellbeing</li> </ul>	X				
4. Pain, Distress, Anesthesia and Analgesia	<b>A</b> *	М	S	С	NA
(e.g., thermoregulation, physiologic function, analgesia, infection, removal of skin closures) ( <i>Guide</i> , pp 119-120)					X
<ul> <li>119)</li> <li>Post-operative monitoring and care are provided by trained personnel and documented</li> </ul>					_
For aquatic species, skin surfaces are kept moist during surgical procedures (Guide, p. )					X
<ul> <li>Procedures for monitoring surgical anesthesia and analgesia are in place (Guide, p 119)</li> </ul>					X
sterile packs are in place ( <i>Guide</i> , <u>p 119</u> )					X
<ul> <li>Aseptic technique is followed for survival surgical procedures (<i>Guide</i>, pp 118-119)</li> <li>Effective procedures for sterilizing instruments and monitoring expiration dates on</li> </ul>					X
are clean ( <i>Guide</i> , <u>p 118</u> )					X
<ul> <li>For nonsurvival surgery, the site is clipped, gloves are worn and instruments and area</li> </ul>					
<ul> <li>Surgical procedures including laparoscopic procedures are categorized as major or minor (Guide, pp 117-118)</li> </ul>					Х
<ul> <li>Aseptic surgery is conducted in dedicated facilities or spaces, unless exception justified and IACUC approved (Guide, p 116)</li> </ul>					X
<ul> <li>Pre-surgical plans are developed and include veterinary input (e.g., location, supplies, anesthetic and analgesic use, peri-operative care, recordkeeping) (Guide, p 116)</li> </ul>					X
<ul> <li>Researchers have appropriate training to ensure good technique (Guide, p 115)</li> <li>[must]</li> </ul>					X
• Surgical outcomes are assessed and corrective changes instituted (Guide, p 115)					X
3. Surgery	<b>A</b> *	М	S	С	N/
<ul> <li>Diagnostic resources are available for preventive health program (Guide, p 112)</li> </ul>	X				
<ul> <li>Policies in place for isolation of sick animals (<i>Guide</i>, <u>p 112</u>) Just euthanized</li> <li>Program is in place for surveillance, diagnosis, treatment and control of disease to include daily observation (<i>Guide</i>, <u>p 112</u>)</li> </ul>	X				X
Procedures in place for stabilization/acclimation ( <i>Guide</i> , pp 110-111)	X				V
<ul> <li>Procedures in place for quarantine to include zoonoses prevention (<i>Guide</i>, <u>p 110</u>)</li> <li>Quarantined animals from different shipments are handled separately or physically separated (<i>Guide</i>, <u>p 110</u>)</li> </ul>					X
<ul> <li>Environment at receiving site is appropriate (Guide, p 109)</li> <li>Policies in place on separation by species, source, and health status (Guide, pp 109, 111-112)</li> </ul>	X				
<ul> <li>Appropriate loading and unloading facilities are available (Guide, p 109)</li> </ul>	X				_
<ul> <li>Movement of animals is planned to minimize transit time and deliveries are planned to ensure receiving personnel are available (Guide, pp 107- 108)</li> </ul>	X				
<ul> <li>Transportation is planned to ensure safety, security and minimize risk (Guide, p 107)</li> </ul>	X				<u> </u>

	are provided during training (Guide, p 121)					
	Selection of analgesics and anesthetics is based on professional veterinary judgment					
	(Guide, p 121)	X				
	Painful procedures are monitored to ensure appropriate analgesic management					
	(Guide, p 122)					X
	<ul> <li>Nonpharmacologic control of pain is considered as an element of postprocedural care (Guide, p 122)</li> </ul>					X
	<ul> <li>Procedures are in place to assure antinoception before surgery begins (Guide, p 122)</li> <li>[must]</li> </ul>					X
	<ul> <li>Guidelines for selection and use of analgesics and anesthetics are in place and regularly reviewed and updated (Guide, p 122)</li> </ul>	X				
	<ul> <li>Special precautions for the use of paralytics are in place to ensure anesthesiaxiv (Guide, p 123)</li> </ul>					X
5.	Euthanasia	$\mathbf{A}^*$	М	s	С	NA
	<ul> <li>Methods are consistent with AVMA Guidelines on Euthanasia unless approved by the IACUC (Guide, p 123)</li> </ul>	X				
	<ul> <li>Standardized methods are developed and approved by the veterinarian and IACUC that avoid distress and consider animal age and species (Guide, pp 123-124)</li> </ul>	X				
	<ul> <li>Training is provided on appropriate methods for each species and considers psychological stress to personnel (Guide, p 124)</li> </ul>	X				
	<ul> <li>Procedures and training are in place to ensure death is confirmed (Guide, p 124)</li> <li>[must] In progress as well</li> </ul>	X				
6.	Drug Storage and Control	<b>A</b> *	М	s	С	NA
	<ul> <li>Program complies with federal regulations for human and veterinary drugs(Guide, p 115) [must]</li> </ul>					X
	<ul> <li>Drug records and storage procedures are reviewed during facility inspections (Guide, p 115)</li> </ul>					X
	Procedures are in place to ensure analgesics and anesthetics are used within expiration date (Guide, p 122) [must]	X				
	<ul> <li>Anesthetics and analgesics are acquired, stored, and their use and disposal are recorded legally and safely (Guide, p 122)</li> </ul>	X				
*	A = acceptable					

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NA = not applicable

# Aquatic Animal Housing and Support Areas

Date: 12/12/2019 Location: ACESD

		$\mathbf{A}^*$	M	S	С	N/
•	Location:					
	o animal areas separate from personnel areas (Guide, p 134)	X				
	o separation of species (Guide, p 111)	X				
	o separation by disease status (Guide, p 111)					X
	o security and access control ( <i>Guide</i> , p 151)	X				
,	Construction:					
	o corridors (Guide, p 136)	X				
	o animal room doors ( <i>Guide</i> , pp 137, 150) Doors are under construction				X	
	o exterior windows ( <i>Guide</i> , <u>p 137</u> )					X
	o floors (Guide, pp 137, 150)	X				
	o drainage ( <i>Guide</i> , <u>pp 138</u> , <u>150</u> )	X				
	o walls and ceilings ( <i>Guide</i> , pp 138, 150)	X				
	o heating ventilation and air conditioning (Guide, pp 139, 150-151)	X				
	o power and lighting ( <i>Guide</i> , pp 141, 150)	X				
	o noise control (Guide, p 142)	X				
	o vibration control (Guide, p 142)	X				
	o environmental monitoring (Guide, p 143)	X				
,	Water Quality: X					
	standards for acceptable quality are established ( <i>Guide</i> , <u>p 78</u> )					X
	o chlorine, chloramines, chemical, and reactive bioproducts are removed or neutralized prior to use in aquatic systems ( <i>Guide</i> , pp78, 86) [must]	X				
•	Life Support System:					
	<ul> <li>water source is based on appropriate controls and research requirements (Guide, p 79)</li> </ul>	X				
	o biofilter is of sufficient size to process bioload (Guide, p 80) [must]					X
,	Temperature, Humidity and Ventilation/Illumination/Noise and Vibration:					
	o temperature and humidity ( <i>Guide</i> , pp 43, 80-81)	X				
	o ventilation and air quality ( <i>Guide</i> , pp 45, 81)	X				
	o illumination (Guide, pp 47, 81)	X				
_						

	o noise and vibration ( <i>Guide</i> , pp 49, <u>81</u> )	X	
•	Primary Enclosure:	37	
	o allows for normal physiological and behavioral needs ( <i>Guide</i> , <u>p 82</u> )	X	
	<ul> <li>allows social interaction for social species (Guide, p 82)</li> </ul>	X	
	o provides a balanced, stable environment ( <i>Guide</i> , <u>p 82</u> )	X	
	o provides appropriate water quality and monitoring (Guide, p 82)	X	
	o allows access to food and waste removal (Guide, p.82)	X	
	o restricts escape and entrapment ( <i>Guide</i> , <u>p 82</u> )	X	
	o allows undisturbed observation ( <i>Guide</i> , <u>p.82</u> )	X	
	o constructed of nontoxic materials ( <i>Guide</i> , <u>p 82</u> )	X	
	o prevents electrical hazards ( <i>Guide</i> , <u>p 82</u> )	X	
	<ul> <li>space needs of species are evaluated by IACUC during program evaluations and facility inspections (<i>Guide</i>, p 83)</li> </ul>	X	
•	Environmental Enrichment, Social Housing, Behavioral and Social Manageme	nt:	
	o enrichment elicits appropriate behaviors and is safe (Guide, p.83)	X	
	<ul> <li>semi-aquatic reptiles are provided terrestrial areas (Guide, p 83)</li> </ul>		X
	<ul> <li>handling is kept to a minimum and appropriate techniques are in place at facility or protocol level (Guide, p 84)</li> </ul>	X	
	<ul> <li>nets are cleaned, disinfected and managed to avoid contamination of systems (Guide, p 84)</li> </ul>	X	
•	Food:		
	<ul> <li>storage to prevent contamination, preserve nutrients and prevent pests (Guide, p 84)</li> </ul>	X	
	o delivery ensures access to all , minimizing aggression and nutrient loss ( <i>Guide</i> , $\underline{p}$ 84)	X	
	<ul> <li>storage times are based on manufacturer recommendations or accepted practice (Guide, p 84)</li> </ul>	X	
	o a nutritionally complete diet is provided ( <i>Guide</i> , <u>p 84</u> )	X	
•	Substrate:		
	<ul> <li>amount, type and presentation of substrate is appropriate for the system and the species (Guide, <u>p 85</u>)</li> </ul>	X	
•	Sanitation, Cleaning and Disinfection		
	<ul> <li>frequency of tank/cage cleaning and disinfection is determined by water quality, permits adequate viewing and health monitoring (<i>Guide</i>, <u>p 86</u>)</li> </ul>	X	
	o cleaning and disinfection of macroenvironment (Guide, p. 86)	X	
•	Waste Disposal:	X	
	o procedures for collection ( <i>Guide</i> , pp 73-74)	X	

0	hazardous wastes are rendered safe before removal from facility ( <i>Guide</i> , pp 73-74) [must]	X
• Pe	animal carcasses ( <i>Guide</i> , pp 73-74)	X
0	regularly scheduled ( <i>Guide</i> , p 74)	X
。 • En	documented program including control of pests and insecticide use (Guide, p 74) nergency, Weekend, and Holiday Animal Care:	X
0	care provided by qualified personnel every day ( <i>Guide</i> , pp 74, 87)	X
0	provision for accessible contact information ( <i>Guide</i> , pp 74, 87)	X
0	emergency response plans in place to address major system failures ( <i>Guide</i> , <u>87</u> )	X
0	veterinary care available after hours, weekends, and holidays ( <i>Guide</i> , pp 74, 114)  [must]	X
• 1d	entification:	X
0	cage/tank cards contain required information ( <i>Guide</i> , pp 75, 87) genotype information included and standardized nomenclature used when applicable ( <i>Guide</i> , pp 75, 87)	X
• Re	ecordkeeping:	X
0	water quality parameters and frequency of testing recorded ( <i>Guide</i> , p 88)	X
0	records kept on feeding, nonexpired food supplies, live cultures ( <i>Guide</i> , p 88)	X
	orage:	X
0	adequate space for equipment, supplies, food, substrate and refuse ( $Guide$ , $p$ $141$ )	X
0	substrate protected from contamination ( <i>Guide</i> , p 141)	X
0	food in vermin-free, temperature and humidity controlled area and protected from contamination ( <i>Guide</i> , p 141)	x
0	refuse storage is separate ( <i>Guide</i> , <u>p 141</u> )	X
0	carcass and animal tissue storage is separate, refrigerated below 7°C and cleanable ( <i>Guide</i> , p 141)	X
• Pe	rsonnel:	
0	adequate space for locker rooms, administration and training (Guide, p 135)	X

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**NA** = not applicable

## Cagewash

Date: 12/12/2019 Location: ACESD

		<b>A</b> *	М	s	С	NA
• C	onstruction and Operation: Cage wash meets their needs					$\overline{}$
0	dedicated central area for sanitizing cages and equipment is provided ( <i>Guide</i> , <u>p</u> <u>143</u> )	X				
0	cage-washing equipment meets need (Guide, p 143)	X				
0	doors, windows, floors, drainage, walls, ceilings (Guide, pp 136-138)					X
0	convenient to animal areas/waste disposal (Guide, p 143)	X				
0	ease of access (including door size) facilitates use (Guide, p 143)	X				
0	sufficient space for staging and maneuvering (Guide, p 143)	X				
0	safety precautions/clothing/equipment used for waste disposal/prewash/acid wash ((Guide, p 143))	X				
0	traffic flow clean to dirty with no contamination of clean equipment by dirty equipment and appropriate air pressurization (Guide, p 143)	X				
0	insulation and/or sound attenuation present as needed ( <i>Guide</i> , p 143)					X
0	utilities are appropriate ( <i>Guide</i> , <u>p 143</u> )	X				
0	ventilation meets heat and humidity load (Guide, p 143)	X				
0	safety features (e.g., SOPs, warning signs, eyewash stations) are in use ( <i>Guide</i> , p 143)	X				
0	<u> </u>	X				
0	cage wash temperatures are monitored and records are available (Guide, p 73)	X				
0	appropriate clean cage storage ( <i>Guide</i> , <u>p 141</u> )	X				

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## **II. Semiannual Program Review and Facility Inspection Report**

Date: 12/12/2019

Members in Attendance: Exemption 6Exemption 6Exemption 6Exemption 6

Deficiency Category*	<b>√</b>	Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date Complete
М		Wetlab	Emergency Eye Wash needs 18 inches of egress. Move chair to another location.			12/12/2019
М		Wetlab- G15	Rusty scrapers. Replace rusty scrapers with new scrapers.			12/19/2019
М		Wetlab- Tank 21A & another tank	Rusty clipboards (2). Replace rusty clipboards with new clipboards.			12/19/2019
М		Wetlab	Ambient salinity tubings are dirty. Replace with new tubing. In progress as newer type of replacement tubing is on order			01/07/2020
М		Wetlab	Emergency Eye Wash needs 18 inches of egress. Move boot rack to another location.			12/12/2019

<sup>\*</sup> **A** = acceptable

**M** = minor deficiency

**S** = significant deficiency (is or may be a threat to animal health or safety)

**C** = change in program (PHS Policy <u>IV.A.1.a.-i.</u>) (include in semiannual report to IO and in annual report to OLAW)

**NA** = not applicable

<sup>√</sup> Check if repeat deficiency

### III. Endnotes

<sup>1</sup> The PHS Policy requires that Assured institutions comply with the regulations (9 CFR, Subchapter A) issued by the U.S. Department of Agriculture (USDA) under the Animal Welfare Act, as applicable. The endnotes below are specific USDA regulatory requirements that differ from or are in addition to the PHS Policy. This list is not intended to be all inclusive. For additional information please refer to 9 CFR Subchapter A - Animal Welfare.

- 2.31(b)(2) "The Committee shall be composed of a Chairman and at least two additional members;... at least one shall not be affiliated in any way with the facility...such person will provide representation for general community interests in the proper care and treatment of animals." [PHS policy requires 5 members]
- iii 2.32(c)(4) "...No facility employee, Committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulation or standards under the Act." [USDA requirement additional to PHS Policy]
- iv 2.31(d)(5) "...shall conduct continuing reviews of activities...not less than annually." [PHS Policy requires a complete new review every 3 years utilizing all the criteria for initial review]
- <sup>v</sup> 2.31(d)(1)(x) "...no animal will be used in more than one major operative procedure from which it is allowed to recover unless...(it is) justified for scientific reasons...(or is) required as routine veterinary procedure...or other special circumstances as determined by the Administrator on an individual basis." [this last point is an additional USDA justification for multiple survival surgeries]
- vi 2.36 "...each reporting facility shall submit an annual report to the APHIS, AC sector supervisor for the State where the facility is located on or before December 1 of each calendar year." [The USDA annual report has a list of requirements which differ from PHS annual report]
- vii 2.36(b)(3) "...exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the IACUC. A summary of all such exceptions must be attached to the facility's annual report." [Refers to USDA annual report]
- viii 2.31(c)(3) "...Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected shall be reported in writing within 15 business days by the IACUC, through the institutional official, to APHIS and any Federal agency funding that activity." [PHS Policy requires prompt reporting to OPRR of serious or continuing noncompliance with the PHS Policy or serious deviations from the provisions of the *Guide*]
- ix 2.36 "...each reporting facility shall submit an annual report to the APHIS, AC sector supervisor for the State where the facility is located on or before December 1 of each calendar year." [The USDA annual report has a list of requirements which differ from PHS annual report]
- x In addition to PHS requirements for IACUC review/application for funding, USDA regulations require: 2.31(d)(1)(ii) "The principal investigator (PI) consider alternatives to procedures that cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources...used to determine that alternatives were not available."
  - 2.31(d)(1)(iii) "The PI has provided written assurance that the activities do not unnecessarily duplicate previous experiments."
  - 2.31(d)(1)(iv) "Procedures that may cause more than momentary or slight pain or distress to the animals will:
    - involve in their planning, consultation with the attending veterinarian or his or her designee; [PHS Policy does not specify veterinary consultation]
    - not include paralytics without the use of anesthesia;"

ii Part 2 Subpart C - Research Facilities

- 2.31(d)(1)(x) "No animal will be used in more than one major operative procedure from which it is allowed to recover, unless justified for scientific reasons by the principal investigator, in writing..."
- xi 2.33(a)(1) "In the case of a part-time attending veterinarian or consultant arrangements, the formal arrangements shall include a written program of veterinary care and regularly scheduled visits to the research facility." [USDA requirement additional]
- xii 2.32(c) "Humane methods of animal maintenance and experimentation, including the basic needs of each species, proper handling and care for the various species of animals used by the facility, proper pre-procedural and post-procedural care of animals, and aseptic surgical methods and procedures."
- xiii 2.32(c) additional specifications include:
- "proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility"
- "methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility..."
- "utilization of services (e.g., National Agricultural Library, National Library of Medicine) to provide information on appropriate animal care and use, alternatives to the use of live animals in research , that could prevent unintended and unnecessary duplication of research involving animals, and regarding the intent and requirements of the Act." [USDA training specifications are more detailed than PHS Policy].
- $^{xiv}$  2.31(d)(iv)(C) "Procedures that may cause more than momentary or slight pain or distress to the animals will...not include the use of paralytics without anesthesia."

### **Semiannual Program Review and Facility Inspection Checklist**

#### About the checklist

The Semiannual Program Review and Facility Inspection Checklist is provided to assist institutions in conducting their semiannual reviews of programs and facilities for the care and use of animals. The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy), section IV.B.1.-2., requires the Institutional Animal Care and Use Committee (IACUC) to review the institution's program for humane care and use of animals and inspect all of the institution's animal facilities at least once every 6 months using the Guide for the Care and Use of Laboratory Animals: Eighth Edition (Guide) as a basis for evaluation.

#### How to use the checklist

This checklist is a tool to assist IACUCs in conducting thorough semiannual reviews. IACUCs are not required to use this checklist but are encouraged to amend it as necessary to reflect institutional programs and needs, or to develop their own checklist. If the checklist is modified, periodic review of the checklist is recommended to ensure relevant topics are considered as the animal care and use program changes.

The checklist covers the major topics of the *Guide* and the requirements of the PHS Policy. The checklist does not replace the *Guide*, but should be utilized in conjunction with the *Guide*. The *Guide* provides the standards, recommendations, and descriptions of desired outcomes necessary to evaluate and inspect an animal care and use program. Relevant references for the *Guide* and the PHS Policy are noted. Endnotes are included to reference specific U.S. Department of Agriculture (USDA) regulatory requirements that differ from the PHS Policy. Topics that are new to this version of the checklist or identified as a "must" in the *Guide* are highlighted. A column to identify changes that have occurred in the institution's program for animal care and use (PHS Policy IV.A.1.a.-i.) since the last review is also a new feature.

The checklist consists of the following sections:

- I. Semiannual Program Review Checklist
  - Institutional Policies and Responsibilities
  - Veterinary Care
- II. Semiannual Facility Inspection Checklist
  - Terrestrial Animal Housing and Support Areas
  - Aquatic Animal Housing and Support Areas
  - Cagewash
  - Special Facilities: Aseptic Surgery
  - Special Facilities: Procedure Areas, Non-survival Surgeries, Laboratories, Rodent Surgeries, Imaging, Whole Body Irradiation, Hazardous Agent Containment, Behavioral Studies
- III. Semiannual Program Review and Facility Inspection Report
- IV. Endnotes

It is recommended that the Program Review section be completed during an IACUC meeting. Because physical aspects of a program require visual observation to evaluate, it is recommended that the Facility Inspection section be completed during an inspection of the facilities, including satellite facilities.

A table is provided, "Semiannual Program Review and Facility Inspection Report," as a format for the IACUC to organize and track information regarding deficiencies, and plans and schedules for correction. IACUCs may choose to attach the table to the Semiannual Report to the Institutional Official.

### Questions or comments?

Suggestions or comments about this checklist should be e-mailed to: olawdpe@mail.nih.gov.

# I. Semiannual Program Review Checklist i

## Institutional Policies and Responsibilities: Gulf Breeze

Date: 02/19/2020

1. A	nimal Care and Use Program 🗚	$\mathbf{A}^*$	М	S	С	NA
•	Responsibility for animal well-being is assumed by all members of the program ( <i>Guide</i> , <u>p 1</u> ) [must]	X				
•	IO has authority to allocate needed resources (Guide, p 13)	X				
•	Resources necessary to manage program of veterinary care are provided ( <i>Guide</i> , <u>p 14</u> ) [must]	X				
•	Sufficient resources are available to manage the program, including training of personnel in accord with regulations and the <i>Guide</i> ( <i>Guide</i> , pp 11, 15)	X				
•	Program needs are regularly communicated to IO by AV and/or IACUC (Guide, p 13)	X				
•	Responsibilities for daily animal care and facility management are assigned to specific individual(s) when a full-time veterinarian is not available on site ( <i>Guide</i> , p 14) [must]	X				
•	Inter-institutional collaborations are described in formal written agreements ( <i>Guide</i> , <u>p</u> 15)					X
•	Written agreements address responsibilities, animal ownership, and IACUC oversight (Guide, p 15)					X
2. D	isaster Planning and Emergency Preparedness 🕬	$\mathbf{A}^*$	М	s	С	NA
•	Disaster plans for each facility to include satellite locations are in place ( <i>Guide</i> , <u>p 35</u> , <u>p 75</u> ) [must]	X				
•	Plans include provisions for euthanasia ( <i>Guide</i> , <u>p 35</u> ) [must]	X				
•	Plans include triage plans to meet institutional and investigators' needs (Guide, p 35)	X				
•	Plans define actions to prevent animal injury or death due to HVAC or other failures ( <i>Guide</i> , <u>p 35</u> )	X				
•	Plans describe preservation of critical or irreplaceable animals ( <i>Guide</i> , <u>p 35</u> )					X
•	Plans include essential personnel and their training ( <i>Guide</i> , <u>p 35</u> )  Animal facility plans are approved by the institution and incorporated into overall response plan ( <i>Guide</i> , <u>p 35</u> )	X				
•	Law enforcement and emergency personnel are provided a copy and integration with overall plan is in place ( <i>Guide</i> , p 35)	X				
3. I <i>l</i>	ACUC NEW	$\mathbf{A}^*$	М	s	С	NA
•	Meets as necessary to fulfill responsibilities (Guide, p 25) [must]	X				
•	IACUC Members named in protocols or with conflicts recuse themselves from protocol decisions ( <i>Guide</i> , <u>p 26</u> ) [must]	X				
•	Continuing IACUC oversight after initial protocol approval is in place (Guide, p 33)	X				
•	IACUC evaluates the effectiveness of training programs ( <i>Guide</i> , <u>p 15</u> )	X				
4. I	ACUC Protocol Review - Special Considerations	$\mathbf{A}^*$	М	S	С	NA
•	Humane endpoints are established for studies that involve tumor models, infectious diseases, vaccine challenge, pain modeling, trauma, production of monoclonal antibodies, assessment of toxicologic effects, organ or system failure, and models of cardiovascular shock ( <i>Guide</i> , p 27)	X				
•	For pilot studies, a system to communicate with the IACUC is in place ( <i>Guide</i> , <u>p 28</u> )	X				
•	For genetically modified animals, enhanced monitoring and reporting is in place ( <i>Guide</i> , p 28)					x
•	Restraint devices are justified in the animal use protocols (Guide, p 29) [must]					X
•	Alternatives to physical restraint are considered ( <i>Guide</i> , <u>p 29</u> )					X
•	Period of restraint is the minimum to meet scientific objectives (Guide, p 29)					X
•	Training of animals to adapt to restraint is provided (Guide, p 29)					X
	Animals that fail to adapt are removed from study (Guide, p 29)					X

Appropriate observation intervals of restrained animals are provided (Guide, p 29)	Τ				X
<ul> <li>Veterinary care is provided if lesions or illness result from restraint (Guide, p 30)</li> </ul>	_				^ <b>`</b>
[must]	<u> </u>				X
<ul> <li>Explanations of purpose and duration of restraint are provided to study personnel (Guide, p 30)</li> </ul>					X
<ul> <li>Multiple surgical procedures on a single animal are justified and outcomes evaluated (Guide, p 30)</li> </ul>					X
<ul> <li>Major versus minor surgical procedures are evaluated on a case-by-case basis (Guide, p 30)</li> </ul>					X
<ul> <li>Multiple survival procedure justifications in non-regulated species conform to regulated species standards (Guide, p 30)</li> </ul>	t				X
<ul> <li>Animals on food/fluid restriction are monitored to ensure nutritional needs are met (Guide, p 31)</li> </ul>					)
<ul> <li>Body weights for food/fluid restricted animals are recorded at least weekly (Guide, p 31)</li> </ul>					>
Daily written records are maintained for food/fluid restricted animals (Guide, p 31)					)
<ul> <li>Pharmaceutical grade chemicals are used , when available, for animal-related procedures (Guide, p 31)</li> </ul>				Х	
<ul> <li>Non-pharmaceutical grade chemicals are described, justified, and approved by IACUC (Guide, p 31)</li> </ul>				X	
<ul> <li>Investigators conducting field studies know zoonotic diseases, safety issues, laws and regulations applicable in study area (Guide, p 32)</li> </ul>	x				
<ul> <li>Disposition plans are considered for species removed from the wild (Guide, p 32)</li> </ul>	X				
<ul> <li>Toe-clipping only used when no alternative, performed aseptically and with pain relief (Guide, p 75)</li> </ul>					,
. IACUC Membership and Functions	<b>A</b> *	М	s	С	N
<ul> <li>IACUC is comprised of at least 5 members, appointed by CEO (PHS Policy, <u>IV.A.3.</u>)</li> </ul>	X				Π
<ul> <li>Members include a veterinarian, a scientist, a nonscientist, and a nonaffiliated non-lab animal user (Guide, p 24)<sup>ii</sup></li> </ul>	x				Γ
<ul> <li>IACUC authority and resources for oversight and evaluation of institution's program are provided (Guide, p 14)</li> </ul>	X				
<ul> <li>IACUC conducts semiannual evaluations of institutional animal care and use program (PHS Policy, IV.B.)</li> </ul>	X				
<ul> <li>Conducts semiannual inspections of institutional animal facilities (PHS Policy, <u>IV.B.</u>)</li> </ul>	X				L
• IACUC organizationally reports to the Institutional Official (PHS Policy, IV.A.1.b.)	X				
<ul> <li>Methods for reporting and investigating animal welfare concerns are in place (Guide, p 23) [must]</li> </ul>	X				
<ul> <li>Reviews and investigates concerns about animal care and use at institution<sup>iii</sup> (PHS Policy, <u>IV.B.</u>)</li> </ul>	X				
<ul> <li>Procedures are in place for review, approval, and suspension of animal activities<sup>iv</sup> (PHS Policy, <u>IV.B.</u>)</li> </ul>	X				
<ul> <li>Procedures are in place for review and approval of significant changes to approved activities (PHS Policy, <u>IV.B.</u>)</li> </ul>	X				
Policies are in place for special procedures (e.g., genetically modified animals, restraint, multiple survival surgery, food and fluid regulation, field investigations, and fluid regulation and fluid regulation.					,
<ul> <li>agricultural animals) (Guide, p 27-32)</li> <li>Requests for exemptions from major survival surgical procedure restrictions are made to USDA/APHIS* (Guide, p 30) [must]</li> </ul>					\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \
. IACUC Training	<b>A</b> *	М	S	С	
. IACUC Halling VVV	A	P	3		14
<u> </u>	T 34				Т
All IACUC members should receive:	X		i .	1	
<ul> <li>All IACUC members should receive:</li> <li>Formal orientation to institution's program (Guide, p 17)</li> </ul>	X				T
<ul> <li>All IACUC members should receive:</li> <li>Formal orientation to institution's program (Guide, p 17)</li> <li>Training on legislation, regulations, guidelines, and policies (Guide, p 17)</li> </ul>	X				
<ul> <li>All IACUC members should receive:</li> <li>Formal orientation to institution's program (Guide, p 17)</li> </ul>	_				
<ul> <li>All IACUC members should receive:         <ul> <li>Formal orientation to institution's program (Guide, p 17)</li> <li>Training on legislation, regulations, guidelines, and policies (Guide, p 17)</li> <li>Training on how to inspect facilities and labs where animal use or housing occurs</li> </ul> </li> </ul>	X				

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	o Research investigators, instructors, technicians, trainees, and students ( <i>Guide</i> , pp	.,				
•	16-17) Continuing education for program and research staff provided to ensure high quality	X				
	care and reinforce training ( <i>Guide</i> , <u>pp 16-17</u> )	X				_
•	Training is available prior to starting animal activity (Guide, p 17)	X				
•	Training is documented (Guide, p 15)	X				
•	Training program content includes: (Guide, p 17)	v				
	Methods for reporting concerns ( <i>Guide</i> , <u>p 17</u> )	X				
	Humane practices of animal care (e.g., housing, husbandry, handling) xii	X				
	<ul> <li>Humane practices of animal use (e.g., research procedures, use of anesthesia, pre- and post-operative care, aseptic surgical techniques and euthanasia (Guide, p</li> </ul>					
	17)xiii	X				
	<ul> <li>Research/testing methods that minimize numbers necessary to obtain valid results (PHS Policy, <u>IV.A.1.q.</u>)</li> </ul>	X				
	<ul> <li>Research/testing methods that minimize animal pain or distress (PHS Policy, IV.A.1.q.)</li> </ul>	х				
	o Use of hazardous agents, including access to OSHA chemical hazard notices where					
	applicable ( <i>Guide</i> , <u>p 20</u> )	X				
	o Animal care and use legislation ( <i>Guide</i> , <u>p 17</u> )	X				
	o IACUC function (Guide, p 17)	X				
	<ul> <li>Ethics of animal use and Three R's (Guide, p 17)</li> </ul>	X				
10	Occupational Haalth and Cafety of Bayesman	<b>A</b> *		_	_	NI A
10. •	Occupational Health and Safety of Personnel  Program is in place and is consistent with federal, state, and local regulations (Guide,	<b>A</b> *	M	S	C	NA
•	<u>p 17</u> ) [must]	X				
•	Program covers all personnel who work in laboratory animal facilities (Guide, p 18)	X				
•	Changing, washing, and showering facilities are available as appropriate (Guide, p 19)	X				
•	Hazardous facilities are separated from other areas and identified as limited access (Guide, p 19)	Х				
•	Personnel training is provided based on risk (e.g., zoonoses, hazards, personal					
	hygiene, special precautions, animal allergies) (Guide, p 20)	X				
•	Personal hygiene procedures are in place (e.g., work clothing, eating/drinking/smoking					
	policies) (Guide, p 20)	X				_
•	Procedures for use, storage, and disposal of hazardous biologic, chemical, and physical agents are in place ( $Guide$ , $p$ 21)	X				
•	Personal Protective Equipment for the work area is appropriate and available ( <i>Guide</i> , p					
	<u>21</u> )	X				
•	Program for medical evaluation and preventive medicine for personnel includes:		I			
	<ul> <li>Pre-employment evaluation including health history (Guide, p 22)</li> </ul>					X
	o Immunizations as appropriate (e.g., rabies, tetanus) and tests as appropriate	x				
	(Guide, p 22)  o Zoonosis surveillance as appropriate (e.g., Q-fever, tularemia, Hantavirus, plague)	^				
	(Guide, p 23)					X
	<ul> <li>Procedures for reporting and treating injuries, including accidents, bites, allergies,</li> </ul>					
	etc. ( <i>Guide</i> , <u>p 23</u> )	X				
	<ul> <li>Promotes early diagnosis of allergies including preexisting conditions (Guide, p 22)</li> </ul>					X
	<ul> <li>Considers confidentiality and other legal factors as required by federal, state and local regulations (Guide, p 22) [must]</li> </ul>	X				
	<ul> <li>If serum samples are collected, the purpose is consistent with federal and state laws (Guide, p 22) [must]</li> </ul>					X
•	Waste anesthetic gases are scavenged (Guide, p 21)	X				
•	Hearing protection is provided in high noise areas (Guide, p 22)	X				
•	Respiratory protection is available when performing airborne particulate work (Guide,					Х
	<u>p 22</u> )					

	<ul> <li>Tuberculosis screening provided for all exposed personnel (Guide, p 23)</li> </ul>					X
	<ul> <li>Training and implementation of procedures for bites, scratches, or injuries associated with macaques (Guide, p 23)</li> </ul>					х
	<ul> <li>PPE is provided including gloves, arm protection, face masks, face shields, or goggles (Guide, p 21)</li> </ul>					x
	<ul> <li>Injuries associated with macaques are carefully evaluated and treatment implemented (Guide, p 23)</li> </ul>					X
•	Occupational safety and health of field studies is reviewed by OSH committee or office (Guide, p 32)					x
11.	Personnel Security	<b>A</b> *	М	s	С	NA
•	Preventive measures in place include pre-employment screening, and physical and IT security ( $Guide$ , $p$ 23)	x				
12.	Investigating & Reporting Animal Welfare Concerns №	<b>A</b> *	М	s	С	NA
•	Methods for investigating and reporting animal welfare concerns are established (Guide, p 23) [must]	X				
•	Reported concerns and corrective actions are documented (Guide, p 24)	X				
•	Mechanisms for reporting concerns are posted in facility and at applicable website with instructions ( <i>Guide</i> , p 24)	X				
	o Includes multiple contacts (Guide, p 24)	X				
	<ul> <li>Includes anonymity, whistle blower policy, nondiscrimination and reprisal protection (Guide, p 24)</li> </ul>	x				

A = acceptable

**M** = minor deficiency

S = significant deficiency (is or may be a threat to animal health or safety)
C = change in program (PHS Policy <u>IV.A.1.a.-i.</u>) (include in semiannual report to IO and in annual report to OLAW)

NA = not applicable

# **Veterinary Care**

Date: 02/19/2020

. Clinical Care and Management NEW	<b>A</b> *	M	S	С	N/
<ul> <li>Veterinary program offers high quality of care and ethical standards (Guide, p 105)</li> <li>[must]</li> </ul>	X				
<ul> <li>Veterinarian provides guidance to all personnel to ensure appropriate husbandry, handling, treatment, anesthesia, analgesia, and euthanasia (Guide, p 106)</li> </ul>	X				
Veterinarian provides oversight to surgery and perioperative care ( <i>Guide</i> , p 106)					X
<ul> <li>Veterinary care program is appropriate for program requirements (<i>Guide</i>, pp 113-114)</li> <li>Veterinarian(s) is familiar with species and use of animals and has access to medical and experimental treatment records (<i>Guide</i>, p 114)</li> </ul>	X				
Procedures to triage and prioritize incident reports are in place (Guide, p 114)	Х				Г
Procedures are in place to address:					
<ul> <li>Problems with experiments to determine course of treatment in consultation with investigator(Guide, p 114)</li> </ul>	X				
<ul> <li>Recurrent or significant health problems with the IACUC and documentation of treatments and outcomes (Guide, p 114)</li> </ul>	X				
<ul> <li>Veterinary review and oversight of medical and animal use records (Guide, p 115)</li> </ul>	X				
<ul> <li>Procedures established for timely reporting of animal injury, illness, or disease (Guide, p 114) [must]</li> </ul>	X				
<ul> <li>Procedures established for veterinary assessment, treatment, or euthanasia (Guide, p 114) [must]</li> </ul>	X				
<ul> <li>Veterinarian is authorized to treat, relieve pain, and/or euthanize (Guide, p 114)</li> <li>[must]</li> </ul>	X				
Animal Procurement and Transportation/Preventive Medicine	<b>A</b> *	М	S	С	N
<ul> <li>Procedures for lawful animal procurement are in place (Guide, p 106) [must]</li> </ul>	X				
• Sufficient facilities and expertise are confirmed prior to procurement (Guide, p 106)	X				
<ul> <li>Procurement is linked to IACUC review and approval (Guide, p 106)</li> </ul>	X				
<ul> <li>Random source dogs and cats are inspected for identification (Guide, p 106)</li> </ul>					X
• Population status of wildlife species is considered prior to procurement (Guide, p 106)	X				
Appropriate records are maintained on animal acquisition (Guide, p 106)	X				
<ul> <li>Animal vendors are evaluated to meet program needs and quality (Guide, p 106)</li> </ul>	X				
<ul> <li>Breeding colonies are based on need and managed to minimize numbers (Guide, p 107)</li> </ul>	X				
<ul> <li>Procedures for compliance with animal transportation regulations, including international requirements, are in place (Guide, p 107) [must]</li> </ul>	X				
• Transportation is planned to ensure safety, security and minimize risk (Guide, p 107)	X				L
<ul> <li>Movement of animals is planned to minimize transit time and deliveries are planned to ensure receiving personnel are available (Guide, pp 107- 108)</li> </ul>	X				
<ul> <li>Appropriate loading and unloading facilities are available (Guide, p 109)</li> </ul>	X				
Environment at receiving site is appropriate (Guide, p 109)	X				
<ul> <li>Policies in place on separation by species, source, and health status (Guide, pp 109, 111-112)</li> </ul>	X				
<ul> <li>Procedures in place for quarantine to include zoonoses prevention (Guide, p 110)</li> </ul>	X				
<ul> <li>Quarantined animals from different shipments are handled separately or physically separated (Guide, p 110)</li> </ul>	X				
Procedures in place for stabilization/acclimation (Guide, pp 110-111)	X				
Policies in place for isolation of sick animals (Guide, p 112)	X				
<ul> <li>Program is in place for surveillance, diagnosis, treatment and control of disease to include daily observation (Guide, p 112)</li> </ul>	X				
Diagnostic resources are available for preventive health program (Guide, p 112)				X	

· _	Surgery	$\mathbf{A}^*$	М	S	С	N
	<ul> <li>Surgical outcomes are assessed and corrective changes instituted (Guide, p 115)</li> </ul>					X
	<ul> <li>Researchers have appropriate training to ensure good technique (Guide, p 115)</li> <li>[must]</li> </ul>	X				
	Pre-surgical plans are developed and include veterinary input (e.g., location, supplies, particular and production and production and production).				Х	
	<ul> <li>anesthetic and analgesic use, peri-operative care, recordkeeping) (Guide, p 116)</li> <li>Aseptic surgery is conducted in dedicated facilities or spaces, unless exception justified</li> </ul>				^	
	<ul> <li>and IACUC approved (<i>Guide</i>, <u>p 116</u>)</li> <li>Surgical procedures including laparoscopic procedures are categorized as major or</li> </ul>					<b>)</b>
	minor ( <i>Guide</i> , pp 117-118)					<b>)</b>
	<ul> <li>For nonsurvival surgery, the site is clipped, gloves are worn and instruments and area are clean (Guide, p 118)</li> </ul>	X				
	<ul> <li>Aseptic technique is followed for survival surgical procedures (Guide, pp 118-119)</li> </ul>					<b>)</b>
	<ul> <li>Effective procedures for sterilizing instruments and monitoring expiration dates on sterile packs are in place (Guide, p 119)</li> </ul>					)
	<ul> <li>Procedures for monitoring surgical anesthesia and analgesia are in place (Guide, p 119)</li> </ul>				Х	
	<ul> <li>For aquatic species, skin surfaces are kept moist during surgical procedures (Guide, p 119)</li> </ul>	X				Γ
	<ul> <li>Post-operative monitoring and care are provided by trained personnel and documented (e.g., thermoregulation, physiologic function, analgesia, infection, removal of skin closures) (Guide, pp 119-120)</li> </ul>					,
		<b>A</b> *	М	S	С	_
	Guidelines for assessment and categorization of pain, distress and animal wellbeing					Ť
	are provided during training ( <i>Guide</i> , p 121)	X				
	<ul> <li>Selection of analgesics and anesthetics is based on professional veterinary judgment (Guide, p 121)</li> </ul>	X				
	<ul> <li>Painful procedures are monitored to ensure appropriate analgesic management (Guide, p 122)</li> </ul>	X				
	<ul> <li>Nonpharmacologic control of pain is considered as an element of postprocedural care (Guide, p 122)</li> </ul>	X				
	<ul> <li>Procedures are in place to assure antinoception before surgery begins (Guide, p 122)</li> <li>[must]</li> </ul>	X				Г
	<ul> <li>Guidelines for selection and use of analgesics and anesthetics are in place and regularly reviewed and updated (Guide, p 122)</li> </ul>	X				Γ
	<ul> <li>Special precautions for the use of paralytics are in place to ensure anesthesiaxiv         (Guide, p 123)</li> </ul>					,
		<b>A</b> *	м	s	С	
	Methods are consistent with AVMA Guidelines on Euthanasia unless approved by the IACUC (Guide, p 123)	X	141			ľ
	Standardized methods are developed and approved by the veterinarian and IACUC that avoid distress and consider animal age and species (Guide, pp 123-124)	X				T
	Training is provided on appropriate methods for each species and considers					t
	psychological stress to personnel ( <i>Guide</i> , <u>p 124</u> )  • Procedures and training are in place to ensure death is confirmed ( <i>Guide</i> , <u>p 124</u> )	X				┝
_	[must]	X				L
		$\mathbf{A}^*$	M	S	С	N
	<ul> <li>Program complies with federal regulations for human and veterinary drugs(Guide, p</li> <li>115) [must]</li> </ul>	X				
	<ul> <li>Drug records and storage procedures are reviewed during facility inspections (Guide, p 115)</li> </ul>	X				
	Procedures are in place to ensure analgesics and anesthetics are used within expiration date ( <i>Guide</i> , p 122) [must]	X				Γ
	expiration date (Guide, D 122) illiusti					1

<sup>\*</sup> A = acceptable

**M** = minor deficiency

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8

**S** = significant deficiency (is or may be a threat to animal health or safety)

**C** = change in program (PHS Policy <u>IV.A.1.a.-i.</u>) (include in semiannual report to IO and in annual report to OLAW)

NA = not applicable

#### **NOTES:**

# **II. Semiannual Facility Inspection Checklist**

#### **Terrestrial Animal Housing and Support Areas**

Date: 02/19/2020

**Location: GEMMD Wetlabs** 

	$\mathbf{A}^*$	M	S	С	NA
Location:					
o animal areas separate from personnel areas ( <i>Guide</i> , <u>p 134</u> )					X
o separation of species ( <i>Guide</i> , <u>p 111</u> )					X
o separation by disease status ( <i>Guide</i> , <u>p 111</u> )					X
o security and access control (Guide, p 151)					X
Construction:	Т	Ι	Ι	I	
o corridors ( <i>Guide</i> , <u>p 136</u> )					X
o animal room doors ( <i>Guide</i> , <u>p 137</u> )	_				X
o exterior windows ( <i>Guide</i> , <u>p 137</u> )					X
o floors ( <i>Guide</i> , <u>p 137</u> )					X
o drainage (Guide, <u>p 138</u> )	<u> </u>				X
o walls and ceilings ( <i>Guide</i> , <u>p 138</u> )	<u> </u>				X
o heating ventilation and air conditioning ( <i>Guide</i> , <u>p 139</u> )					X
o power and lighting ( <i>Guide</i> , <u>p 141</u> )					X
o noise control (Guide, p 142)					X
o vibration control (Guide, p 142)					X
o environmental monitoring (Guide, p 143)					X
Room/Cage:	_	ı			
o temperature and humidity ( <i>Guide</i> , <u>p 43</u> )	<u> </u>				X
o ventilation and air quality ( <i>Guide</i> , <u>p 45</u> )					X
o illumination ( <i>Guide</i> , <u>p 47</u> )					X
o noise and vibration ( <i>Guide</i> , <u>p 49</u> )					X
Primary Enclosure:					
<ul> <li>space meets physiologic, behavioral xv, and socialxvi needs (Guide, pp 51, 55-63)</li> </ul>					X
<ul> <li>secure environment provided (Guide, p 51)</li> </ul>					X
o durable, nontoxic materials in good repair and no risk of injury ( <i>Guide</i> , <u>p 51</u> )					X
o flooring is safe and appropriate for species ( <i>Guide</i> , <u>p 51</u> )	<u> </u>				X
o adequate bedding and structures for resting, sleeping, breeding ( <i>Guide</i> , <u>p 52</u> )	<u> </u>				X
o objective assessments of housing and management are made ( <i>Guide</i> , <u>p 52</u> )					X
<ul> <li>procedures for routine husbandry are documented (Guide, p 52)</li> </ul>					X
o socially housed animals can escape or hide to avoid aggression (Guide, p 55)					X
o cage height provides adequate clearance (Guide, p 56)					X
<ul> <li>animals express natural postures, can turn around, access food and water, and rest away from urine and feces (Guide, p 56) [must]</li> </ul>					x
<ul> <li>rationale<sup>xvii</sup> for Guide/USDA space exceptions approved by IACUC and based on performance indices (Guide, p 56)</li> </ul>					X
o dogs and cats allowed to exercise and provided human interaction (Guide, p 58)					X

0	nonhuman primates are socially housed except for scientific, veterinary or behavior reasons ( <i>Guide</i> , pp 58-59)	
0	single housing of nonhuman primates is for shortest duration possible ( <i>Guide</i> , <u>p</u> 60)	
0	opportunities for release into larger enclosures is considered for single caged nonhuman primates ( <i>Guide</i> , p 60)	
0	agricultural animals are housed socially ( <i>Guide</i> , p 60)	
0	food troughs and water devices for agricultural animals allow access for all animals ( <i>Guide</i> , p 60)	
En	vironmental Enrichment, Behavioral and Social Management:	
0	structures and resources promote species typical behavior ( <i>Guide</i> , pp 52-54)	
0	novelty of enrichment is considered ( <i>Guide</i> , p 53)	
0	species specific plans for housing including enrichment, behavior and activity are developed and reviewed regularly by IACUC, researchers and veterinarian ( <i>Guide</i> , pp 53, 58, 60, 63)	
0	animal care personnel receive training to identify abnormal animal behaviors (Guide, p 53)	
0	stability of pairs or groups is monitored for incompatibility ( <i>Guide</i> , <u>p 64</u> )	
0	single housing is justified for social species ( <i>Guide</i> , <u>p 64</u> )	
0	single housing is limited to the minimum period necessary ( <i>Guide</i> , <u>p 64</u> )	
0	additional enrichment for single housed animals is provided (Guide, p 64)	
0	single housing is reviewed regularly by IACUC and veterinarian ( <i>Guide</i> , <u>p 64</u> )	
o Sh	habituation to routine procedures is part of enrichment program ( <i>Guide</i> , <u>p 64</u> )  eltered or Outdoor Housing: (e.g., barns, corrals, pastures, islands)	
0	weather protection and opportunity for retreat (Guide, p 54) [must]	
0	appropriate size ( <i>Guide</i> , <u>p 54</u> )	
0	ventilation and sanitation of shelter (no waste/moisture build-up) (Guide, p 54)	
0	animal acclimation (Guide, p 55)	
0	social compatibility ( <i>Guide</i> , <u>p 55</u> )	
0	roundup/restraint procedures ( <i>Guide</i> , <u>p 55</u> )	
0	appropriate security ( <i>Guide</i> , <u>p 55</u> )	
Na	turalistic Environments:	
0	animals added /removed with consideration of effect on group (Guide, p 55)	
0	adequate food, fresh water, and shelter ensured (Guide, p 55)	
Fo:	feeding schedule and procedures including caloric intake management ( <i>Guide</i> , pp 65-67)	
0	contamination prevention ( <i>Guide</i> , <u>p 65</u> )	
0	vendor quality control ( <i>Guide</i> , p 66)	
0	storage in sealed containers ( <i>Guide</i> , <u>p 66</u> )	
0	expiration date labeling ( <i>Guide</i> , p 66)	
0	vermin control ( <i>Guide</i> , p 66)	
0	rotation of stocks ( <i>Guide</i> , p 66)	
	iter:	
0	ad libitum unless justified (Guide, pp 67-68)	
0	QC procedures (Guide, pp 67-68)	
Ве	dding and Nesting Materials:	
0	species appropriate ( <i>Guide</i> , <u>pp 68-69</u> )	
	keeps animals dry ( <i>Guide</i> , pp 68-69)	
0	Reeps difficult (Galac, pp 00 05)	
	QC procedures ( <i>Guide</i> , pp 68-69)	

<ul> <li>Sanitat</li> </ul>	ion:	
o freq	uency of bedding/substrate change ( <i>Guide</i> , <u>p 70</u> )	
o clea	ning and disinfection of microenvironment ( <i>Guide</i> , pp 70-71)	
o clea	ning and disinfection of macroenvironment ( <i>Guide</i> , <u>p 72</u> )	
o asse	ssing effectiveness ( <i>Guide</i> , <u>p 73</u> )	
<ul> <li>Waste</li> </ul>	Disposal:	
o prod	edures for collection ( <i>Guide</i> , pp 73-74)	
	edures for storage and disposal (Guide, pp 73-74)	
	ardous wastes are rendered safe before removal from facility ( <i>Guide</i> , <u>pp 73-</u> [must]	
o anin	nal carcasses ( <i>Guide</i> , pp 73-74)	
<ul> <li>Pest Co</li> </ul>	ontrol:	
	larly scheduled ( <i>Guide</i> , <u>p 74</u> )	
(Gu	Imented program including control of rodent pests and insecticide use de, p 74)	
<ul> <li>Emerge</li> </ul>	ency, Weekend, and Holiday Animal Care:	
o care	provided by qualified personnel every day ( <i>Guide</i> , <u>p 74</u> )	
o prov	rision for accessible contact information (Guide, p 74)	
o mor	itoring of backup systems ( <i>Guide</i> , <u>p 143</u> )	
o vete	rinary care available after hours, weekends, and holidays (Guide, pp 74,	
<u>114</u> )	[must]	
o <b>a</b> di	saster plan that takes into account both personnel and animals ( <i>Guide</i> , <u>p 75</u> )	
<ul> <li>Identif</li> </ul>	cation:	
	e/rack cards contain required information (Guide, p 75)	
_	otype information included and standardized nomenclature used when	
	icable ( <i>Guide</i> , <u>p 75</u> )	
	keeping:	
	cal records accessible and contain appropriate information ( <i>Guide</i> , <u>pp 75-76</u> )	
	rds are provided when animals are transferred between institutions (Guide, p	
<u>75</u> ) • Breedii	ng Genetics and Nomenclature:	
	opriate genetic records, management and monitoring procedures ( <i>Guide</i> , <u>p</u>	
<u>76</u> )		
	notypes that affect wellbeing are reported to IACUC and effectively managed	
	de, <u>p 77</u> )	
• Storage		
	quate space for equipment, supplies, food, bedding and refuse ( <i>Guide</i> , p 141)	
	ding in vermin-free area and protected from contamination(Guide, p 141)	
fron	in vermin-free, temperature and humidity controlled area and protected contamination ( <i>Guide</i> , <u>p 141</u> )	
	se storage is separate ( <i>Guide</i> , <u>p 141</u> )	
clea	ass and animal tissue storage is separate, refrigerated below 7°C and nable ( <i>Guide</i> , <u>p 141</u> )	
<ul> <li>Person</li> </ul>	nel:	
o ade	quate space for locker rooms, administration and training (Guide, p 135)	

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**NA** = not applicable

# Aquatic Animal Housing and Support Areas

Date: 02/19/2020 Location: GEMMD Wetlabs

_	Location:	<b>A</b> *	М	S	С	
		X				Т
		X				t
	· · · · · · · · · · · · · · · · · · ·	X				$^{+}$
	separation by disease status ( <i>Guide</i> , <u>p 111</u> )	X				t
	o security and access control (Guide, p 151)  Construction:					_
	o corridors (Guide, p 136)	Т				Ī
	animal room doors ( <i>Guide</i> , pp 137, 150)					t
	exterior windows (Guide, p 137)					t
	floors (Guide, pp 137, 150)	X				t
	o drainage ( <i>Guide</i> , <u>pp 138</u> , <u>150</u> )	X				t
	walls and ceilings ( <i>Guide</i> , pp 138, 150)	X				t
	heating ventilation and air conditioning ( <i>Guide</i> , pp 139, 150-151)	X				†
	power and lighting ( <i>Guide</i> , pp 141, 150)	X				t
		X				†
	· · · · · · · · · · · · · · · · · · ·	X				+
	vibration control (Guide, p 142)	X				+
	o environmental monitoring ( <i>Guide</i> , <u>p 143)</u> Water Quality:					_
	standards for acceptable quality are established ( <i>Guide</i> , p. 78)	X				Ī
	chlorine, chloramines, chemical, and reactive bioproducts are removed or	<del>  ^</del>				t
	neutralized prior to use in aquatic systems (Guide, pp78, 86) [must]	X				
•	Life Support System:					_
(	water source is based on appropriate controls and research requirements (Guide,					
	p 79)	X				+
	biofilter is of sufficient size to process bioload (Guide, p. 80) [must]					
	Temperature, Humidity and Ventilation/Illumination/Noise and Vibration:	X				T
	temperature and humidity ( <i>Guide</i> , pp 43, 80-81)	_				+
	ventilation and air quality ( <i>Guide</i> , <u>pp 45</u> , <u>81</u> )	X				+
	illumination (Guide, pp 47, 81)	X				+
	noise and vibration ( <i>Guide</i> , pp 49, 81)	X				1
	Primary Enclosure:	X				T
	allows for normal physiological and behavioral needs ( <i>Guide</i> , <u>p 82</u> )	X				+
	allows social interaction for social species (Guide, p. 82)	_				+
	provides a balanced, stable environment (Guide, p 82)	X				+
(	provides appropriate water quality and monitoring (Guide, p 82)	X				+
(	allows access to food and waste removal (Guide, p 82)	X				+
(	restricts escape and entrapment ( <i>Guide</i> , <u>p 82</u> )	X				4
(	allows undisturbed observation (Guide, p 82)	X				+
	constructed of nontoxic materials (Guide, p 82)	X				1
(	prevents electrical hazards (Guide, p. 82)	X				1
(			l .			
(	space needs of species are evaluated by IACUC during program evaluations and	Y				
(	space needs of species are evaluated by IACUC during program evaluations and facility inspections ( <i>Guide</i> , p 83)	X ent:				_
•	space needs of species are evaluated by IACUC during program evaluations and					I

	or protocol level ( <i>Guide</i> , <u>p 84</u> ) nets are cleaned, disinfected and managed to avoid contamination of systems	X		
0	(Guide, p 84)	X		
• Foo				
	storage to prevent contamination, preserve nutrients and prevent pests ( $Guide$ , $p$ 84)	X		
	delivery ensures access to all , minimizing aggression and nutrient loss (Guide, $\underline{p}$ 84)	X		
0	storage times are based on manufacturer recommendations or accepted practice ( $Guide$ , $p$ 84)	X		
	a nutritionally complete diet is provided ( <i>Guide</i> , <u>p 84</u> )	X		
	ostrate:			
	amount, type and presentation of substrate is appropriate for the system and the species ( <i>Guide</i> , <u>p 85</u> )			
	nitation, Cleaning and Disinfection frequency of tank/cage cleaning and disinfection is determined by water quality,			
	permits adequate viewing and health monitoring ( <i>Guide</i> , <u>p 86</u> )	X		
	cleaning and disinfection of macroenvironment ( <i>Guide</i> , <u>p 86</u> ) <b>ste Disposal:</b>	<b>A</b>		
	•	X		
	procedures for collection ( <i>Guide</i> , <u>pp 73-74</u> ) hazardous wastes are rendered safe before removal from facility ( <i>Guide</i> , <u>pp 73-</u>	^		
O	74) [must]	X		
0	animal carcasses ( <i>Guide</i> , pp 73-74)	X		
	st Control:			
	regularly scheduled ( <i>Guide</i> , p 74)			
	documented program including control of pests and insecticide use ( <i>Guide</i> , p. 74)			
	ergency, Weekend, and Holiday Animal Care:			
	care provided by qualified personnel every day ( <i>Guide</i> , pp 74, 87)	X		
0	provision for accessible contact information ( <i>Guide</i> , pp 74, 87)	X		
	emergency response plans in place to address major system failures ( <i>Guide</i> , <u>87</u> )	X		
	veterinary care available after hours, weekends, and holidays ( <i>Guide</i> , pp 74, 114)	^		
O	must]	X		
• Ide	entification:			
0	cage/tank cards contain required information ( <i>Guide</i> , pp 75, 87) genotype information included and standardized nomenclature used when		X	
	applicable (Guide, pp 75, 87)			
	cordkeeping:	v		
	water quality parameters and frequency of testing recorded ( <i>Guide</i> , <u>p 88</u> )	X		
	records kept on feeding, nonexpired food supplies, live cultures ( <i>Guide</i> , <u>p 88</u> )	X		
	arage: adequate space for equipment, supplies, food, substrate and refuse ( <i>Guide</i> , <u>p</u>			
	<u>141</u> )	X		
	substrate protected from contamination ( <i>Guide</i> , p 141)	X		
	food in vermin-free, temperature and humidity controlled area and protected from contamination ( <i>Guide</i> , <u>p 141</u> )	X		
0	refuse storage is separate ( <i>Guide</i> , <u>p 141</u> )	X		
0	carcass and animal tissue storage is separate, refrigerated below 7°C and cleanable ( <i>Guide</i> , p 141)	X		
	sonnel:			

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**NA** = not applicable

<b>NOTES:**</b> The Attending Vet had a hard time seeing the fish in their tank visibility of he fish in the tanks. Will discuss this with the Eco-IACUC.	s. The Attending Vet would like better

# Cagewash

Date: 02/19/2020

**Location: GEMMD Wetlabs** 

		$\mathbf{A}^*$	М	S	С	NA
Co	onstruction and Operation:					
0	dedicated central area for sanitizing cages and equipment is provided ( <i>Guide</i> , $\underline{p}$ 143)	X				
0	cage-washing equipment meets need ( <i>Guide</i> , <u>p 143</u> )					X
0	doors, windows, floors, drainage, walls, ceilings (Guide, pp 136-138)					X
0	convenient to animal areas/waste disposal (Guide, p 143)					X
0	ease of access (including door size) facilitates use (Guide, p 143)	X				
0	sufficient space for staging and maneuvering (Guide, p 143)	X				
0	safety precautions/clothing/equipment used for waste disposal/prewash/acid wash (( <i>Guide</i> , p 143)	X				
0	traffic flow clean to dirty with no contamination of clean equipment by dirty equipment and appropriate air pressurization (Guide, p 143)					X
0	insulation and/or sound attenuation present as needed (Guide, p 143)					X
0	utilities are appropriate ( <i>Guide</i> , <u>p 143</u> )	X				
0	ventilation meets heat and humidity load ( <i>Guide</i> , p 143)	X				
0	safety features (e.g., SOPs, warning signs, eyewash stations) are in use ( <i>Guide</i> , p 143)	Х				
0	functioning safety devices to prevent entrapment in washer/sterilizers ( <i>Guide</i> , <u>p</u> 143)					Х
0	cage wash temperatures are monitored and records are available (Guide, p 73)					X
0	appropriate clean cage storage ( <i>Guide</i> , <u>p 141</u> )	X				

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NA = not applicable

## **Special Facilities: Aseptic Surgery**

Date: 02/19/2020

**Location: GEMMD Wetlabs** 

		$\mathbf{A}^*$	M	S	C	N
• Ge	neral Considerations:					
О	location minimizes traffic/contamination (Guide, p 144)					2
0	functional components (surgical support, animal preparation, surgeon scrub,					Г
	operating room, postoperative recovery) are designed and separated (physically					١,
	or otherwise) (Guide, p 144)					Ľ
0	appropriate drug storage, control, expiration date monitoring ( <i>Guide</i> , <u>pp 115</u> , 122)					
	safe sharps disposal system ( <i>Guide</i> , <u>p 74</u> )					
0						Ħ
0	adequate records of anesthesia and perioperative care (Guide, p 122)					-
0	aseptic procedures in use for all survival surgery (Guide, pp 118-119)					L
	perating Room:					Г
0	effective contamination control procedures (Guide, p 144)					ļ
0	effective cleaning procedures/dedicated tools ( <i>Guide</i> , <u>p 145</u> )					L
0	interior surfaces smooth and impervious to moisture ( <i>Guide</i> , <u>p 145</u> )					L
0	HVAC system meets <i>Guide</i> requirements ( <i>Guide</i> , <u>p 145</u> )					L
0	lighting safe and appropriate ( <i>Guide</i> , <u>p 145</u> )					L
0	outlets safe and appropriate (Guide, p 145)					
0	scavenging of anesthetic gases implemented (Guide, p 145)					
• Su	rgical Support:					
0	facility for washing, sterilizing, storing instruments and supplies (Guide, p 145)					
0	autoclave monitoring procedures are implemented ( <i>Guide</i> , pp 119, 145)					Γ
0	storage of autoclaved materials maintains sterility ( <i>Guide</i> , p 145)					Г
0	cold sterilization procedures are appropriate ( <i>Guide</i> , p 119)					T
	imal Preparation: contains large sink to facilitate cleaning of animal and					T
	erative site ( <i>Guide</i> , <u>p 145</u> )					
Su	rgeon Scrub: outside operating room, non-hand-operated sink (Guide, p 145)					
• Po	stoperative Recovery: allows adequate observation, easily cleaned, supports					Γ
ph	ysiologic functions, minimizes risk of injury ( <i>Guide</i> , <u>p 145</u> )					L
• Dr	essing Area: place for personnel to change (Guide, p 145)					

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NA = not applicable

# Special Facilities: Procedure Areas, Non-survival Surgeries, Laboratories, Rodent Surgeries, Imaging, Whole Body Irradiation, Hazardous Agent Containment, Behavioral Studies

Date: 02/19/2020 Location: GEMMD

		$\mathbf{A}^*$	М	S	С	N
Ge	neral Considerations:					
0	labs used to house animals only when scientifically required and limited to					١,
	minimum period necessary ( <i>Guide</i> , <u>p 134</u> )					2
0	drug storage, control, and expiration dates ( <i>Guide</i> , <u>pp 115</u> , <u>122</u> )					2
0	sharps disposal ( <i>Guide</i> , <u>p 74</u> )					2
0	anesthetic monitoring ( <i>Guide</i> , <u>p 120</u> )					2
О	scavenging of anesthetic gases ( <i>Guide</i> , <u>p 21</u> )					]
0	safety features (e.g., SOPs, safety signs, eyewash stations, secure gas cylinders) are in place ( <i>Guide</i> , <u>p 19</u> )					)
0	carcass disposal ( <i>Guide</i> , pp 73-74)					]
Ad	ditional Concerns for Survival Surgery: (rodent and minor procedures only)					
0	rodent survival surgery clean and uncluttered, not used for anything else during surgery ( <i>Guide</i> , <u>p 144</u> )					]
0	records of peri-operative care (Guide, p 120)					
0	aseptic procedures (Guide, pp 118-119)					
0	autoclave monitoring procedures ( <i>Guide</i> , pp 119, 145)					П
0	storage of autoclaved materials ( <i>Guide</i> , <u>p</u> 145)					
0	cold sterilization procedures are appropriate (Guide, p 119)					Γ
	aging/Whole Body Irradiation: NEW					_
0	location of resource limits contamination risk (Guide, p 147)					Π
0	appropriate transportation methods are in place (Guide, p 147)					Γ
0	gas anesthesia provision, scavenging and monitoring are appropriate ( <i>Guide</i> , <u>p</u> 147)					Ī
0	appropriate sensors and ventilation are provided for cryogen gases ( <i>Guide</i> , <u>p</u> 147) [must]					
0	imaging console is located away from radiation source (Guide, p 147)					Γ
Ha	zardous Agent Containment: 🏋					_
0	facility adheres to APHIS, USDA and CDC Select Agent Regulations and other federal, state and local regulations including security measures ( <i>Guide</i> , <u>p 148</u> ) [must]					
Ве	havioral Studies: NEW					_
	facility minimizes airborne transmission of noise and ground-borne transmission of vibration ( <i>Guide</i> , p 149)					Γ
0	floor coverings reduce sound transmission ( <i>Guide</i> , p 149)					Γ
0	testing equipment allows for surface disinfection ( <i>Guide</i> , p 150)					T
0	components that cannot be cleaned are not in ready contact with animals and kept covered when not in use (Guide, p 150)					T
0	housing areas are contiguous with testing areas when appropriate ( <i>Guide</i> , p 150)					t

<sup>\*</sup> A = acceptable

**M** = minor deficiency

S = significant deficiency (is or may be a threat to animal health or safety)

**C** = change in program (PHS Policy <u>IV.A.1.a.-i.</u>) (include in semiannual report to IO and in annual report to OLAW)

NA = not applicable

## III. Semiannual Program Review and Facility Inspection Report

Date: 02/19/2020

Members in Attendance: Jim Harvey, Exemption 6Exemption 6 Exemption 6 , Leslie Jarrell (via phone/Facetime) and

Deficiency Category*	<b>√</b>	Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date Complete
M		Wetlab	Need signage on the experimental bays.  Add PI Name and ACUP number to signage on experimental bay.	Exemption 6 Exemption 6 Exemption 6 Exemption 6 Exemption 6		4/1/2020
WishList		Wetlab	Wooden box steps need to be added to preventative maintenance schedule.	Jim Harvey (JH)		
WishList		Wetlab	Columns supporting head boxes are showing serious rust. Will try to replace columns.	Exemption 6  Exemption (Wetlab manager)		
WishList		Wetlab	Head Boxes in one section are crowded. Will try to uncrowd the boxes and use newer material to match the rest of the head boxes.	_		
WishList		Wetlab	Water Storage Tanks are due for cleaning. Need funds to have this done.			
WishList		Wetlab	Water testing. Need funds to test for heavy metals.			

<sup>\*</sup> **A** = acceptable

**M** = minor deficiency

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**S** = significant deficiency (is or may be a threat to animal health or safety)

**C** = change in program (PHS Policy <u>IV.A.1.a.-i.</u>) (include in semiannual report to IO and in annual report to OLAW)

**NA** = not applicable

Check if repeat deficiency

#### IV. Endnotes

<sup>1</sup> The PHS Policy requires that Assured institutions comply with the regulations (9 CFR, Subchapter A) issued by the U.S. Department of Agriculture (USDA) under the Animal Welfare Act, as applicable. The endnotes below are specific USDA regulatory requirements that differ from or are in addition to the PHS Policy. This list is not intended to be all inclusive. For additional information please refer to 9 CFR Subchapter A - Animal Welfare.

- 2.31(b)(2) "The Committee shall be composed of a Chairman and at least two additional members;... at least one shall not be affiliated in any way with the facility...such person will provide representation for general community interests in the proper care and treatment of animals." [PHS policy requires 5 members]
- iii 2.32(c)(4) "...No facility employee, Committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulation or standards under the Act." [USDA requirement additional to PHS Policy]
- iv 2.31(d)(5) "...shall conduct continuing reviews of activities...not less than annually." [PHS Policy requires a complete new review every 3 years utilizing all the criteria for initial review]
- <sup>v</sup> 2.31(d)(1)(x) "...no animal will be used in more than one major operative procedure from which it is allowed to recover unless...(it is) justified for scientific reasons...(or is) required as routine veterinary procedure...or other special circumstances as determined by the Administrator on an individual basis." [this last point is an additional USDA justification for multiple survival surgeries]
- vi 2.36 "...each reporting facility shall submit an annual report to the APHIS, AC sector supervisor for the State where the facility is located on or before December 1 of each calendar year." [The USDA annual report has a list of requirements which differ from PHS annual report]
- vii 2.36(b)(3) "...exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the IACUC. A summary of all such exceptions must be attached to the facility's annual report." [Refers to USDA annual report]
- viii 2.31(c)(3) "...Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected shall be reported in writing within 15 business days by the IACUC, through the institutional official, to APHIS and any Federal agency funding that activity." [PHS Policy requires prompt reporting to OPRR of serious or continuing noncompliance with the PHS Policy or serious deviations from the provisions of the *Guide*]
- ix 2.36 "...each reporting facility shall submit an annual report to the APHIS, AC sector supervisor for the State where the facility is located on or before December 1 of each calendar year." [The USDA annual report has a list of requirements which differ from PHS annual report]
- x In addition to PHS requirements for IACUC review/application for funding, USDA regulations require: 2.31(d)(1)(ii) "The principal investigator (PI) consider alternatives to procedures that cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources...used to determine that alternatives were not available."
  - 2.31(d)(1)(iii) "The PI has provided written assurance that the activities do not unnecessarily duplicate previous experiments."
  - 2.31(d)(1)(iv) "Procedures that may cause more than momentary or slight pain or distress to the animals will:
    - involve in their planning, consultation with the attending veterinarian or his or her designee; [PHS Policy does not specify veterinary consultation]
    - not include paralytics without the use of anesthesia;"

ii Part 2 Subpart C - Research Facilities

- 2.31(d)(1)(x) "No animal will be used in more than one major operative procedure from which it is allowed to recover, unless justified for scientific reasons by the principal investigator, in writing..."
- xi 2.33(a)(1) "In the case of a part-time attending veterinarian or consultant arrangements, the formal arrangements shall include a written program of veterinary care and regularly scheduled visits to the research facility." [USDA requirement additional]
- xii 2.32(c) "Humane methods of animal maintenance and experimentation, including the basic needs of each species, proper handling and care for the various species of animals used by the facility, proper pre-procedural and post-procedural care of animals, and aseptic surgical methods and procedures."
- xiii 2.32(c) additional specifications include:
- "proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility"
- "methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility..."
- "utilization of services (e.g., National Agricultural Library, National Library of Medicine) to provide information on appropriate animal care and use, alternatives to the use of live animals in research , that could prevent unintended and unnecessary duplication of research involving animals, and regarding the intent and requirements of the Act." [USDA training specifications are more detailed than PHS Policy].
- xiv 2.31(d)(iv)(C) "Procedures that may cause more than momentary or slight pain or distress to the animals will...not include the use of paralytics without anesthesia."
- <sup>xv</sup> Part 3 Subpart A 3.8 "...research facilities must develop, document, and follow an appropriate plan to provide dogs with the opportunity for exercise. In addition the plan must be approved by the attending veterinarian. The plan must provide written standard procedures..."
- xvi Part 3 Subpart D 3.81 "...research facilities must develop, document, and follow an appropriate plan for environment enhancement adequate to promote the psychological well-being of nonhuman primates."
- <sup>xvii</sup> Part 3 Subpart A 3.6(c)(1) "Each dog housed in a primary enclosure must be provided with a minimum amount of floor space, calculated as follows: (length of dog in inches  $+ 6)^2/144 =$  required floor space in square feet)."
- Part 3 Subpart D 3.80 (b) "Primary enclosures [for nonhuman primates] must meet the minimum space requirements provided in this subpart."
- In situations where the USDA regulations and the *Guide* differ with respect to space requirements, the larger of the two must be followed.

### **Semiannual Program Review and Facility Inspection Checklist**

#### About the checklist

The Semiannual Program Review and Facility Inspection Checklist is provided to assist institutions in conducting their semiannual reviews of programs and facilities for the care and use of animals. The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy), section IV.B.1.-2., requires the Institutional Animal Care and Use Committee (IACUC) to review the institution's program for humane care and use of animals and inspect all of the institution's animal facilities at least once every 6 months using the Guide for the Care and Use of Laboratory Animals: Eighth Edition (Guide) as a basis for evaluation.

#### How to use the checklist

This checklist is a tool to assist IACUCs in conducting thorough semiannual reviews. IACUCs are not required to use this checklist but are encouraged to amend it as necessary to reflect institutional programs and needs, or to develop their own checklist. If the checklist is modified, periodic review of the checklist is recommended to ensure relevant topics are considered as the animal care and use program changes.

The checklist covers the major topics of the *Guide* and the requirements of the PHS Policy. The checklist does not replace the *Guide*, but should be utilized in conjunction with the *Guide*. The *Guide* provides the standards, recommendations, and descriptions of desired outcomes necessary to evaluate and inspect an animal care and use program. Relevant references for the *Guide* and the PHS Policy are noted. Endnotes are included to reference specific U.S. Department of Agriculture (USDA) regulatory requirements that differ from the PHS Policy. Topics that are new to this version of the checklist or identified as a "must" in the *Guide* are highlighted. A column to identify changes that have occurred in the institution's program for animal care and use (PHS Policy IV.A.1.a.-i.) since the last review is also a new feature.

The checklist consists of the following sections:

- I. Semiannual Program Review Checklist
  - Institutional Policies and Responsibilities
  - Veterinary Care
- II. Semiannual Facility Inspection Checklist
  - Terrestrial Animal Housing and Support Areas
  - · Aquatic Animal Housing and Support Areas
  - Cagewash
  - Special Facilities: Aseptic Surgery
  - Special Facilities: Procedure Areas, Non-survival Surgeries, Laboratories, Rodent Surgeries, Imaging, Whole Body Irradiation, Hazardous Agent Containment, Behavioral Studies
- III. Semiannual Program Review and Facility Inspection Report
- IV. Endnotes

It is recommended that the Program Review section be completed during an IACUC meeting. Because physical aspects of a program require visual observation to evaluate, it is recommended that the Facility Inspection section be completed during an inspection of the facilities, including satellite facilities.

A table is provided, "Semiannual Program Review and Facility Inspection Report," as a format for the IACUC to organize and track information regarding deficiencies, and plans and schedules for correction. IACUCs may choose to attach the table to the Semiannual Report to the Institutional Official.

#### Questions or comments?

Suggestions or comments about this checklist should be e-mailed to: olawdpe@mail.nih.gov.

# I. Semiannual Program Review Checklist i

## **Institutional Policies and Responsibilities: Gulf Breeze**

Date: 11/21/2019

1. Animal Care and Use Program №₩	$\mathbf{A}^*$	M	S	C	NA
<ul> <li>Responsibility for animal well-being is assumed by all members of the program (Guide p 1) must</li> </ul>	, <b>X</b>				
IO has authority to allocate needed resources (Guide, p 13)	X				
<ul> <li>Resources necessary to manage program of veterinary care are provided (Guide, p 14 [must]</li> </ul>	<b>X</b>				
<ul> <li>Sufficient resources are available to manage the program, including training of personnel in accord with regulations and the Guide (Guide, pp 11, 15)</li> </ul>	х				
Program needs are regularly communicated to IO by AV and/or IACUC (Guide, p 13)	X				
<ul> <li>Responsibilities for daily animal care and facility management are assigned to specific individual(s) when a full-time veterinarian is not available on site (Guide, p 14) [must</li> <li>Inter-institutional collaborations are described in formal written agreements (Guide, p</li> </ul>	X				
<u>15</u> )					X
<ul> <li>Written agreements address responsibilities, animal ownership, and IACUC oversight (Guide, p 15)</li> </ul>					X
2. Disaster Planning and Emergency Preparedness №	$\mathbf{A}^*$	М	s	С	NA
<ul> <li>Disaster plans for each facility to include satellite locations are in place (Guide, p 35, p 75) [must]</li> </ul>					
Plans include provisions for euthanasia ( <i>Guide</i> , <u>p 35</u> ) [must]	X				
• Plans include triage plans to meet institutional and investigators' needs (Guide, p 35)					X
<ul> <li>Plans define actions to prevent animal injury or death due to HVAC or other failures (Guide, p 35)</li> </ul>	X				
Plans describe preservation of critical or irreplaceable animals (Guide, p 35)	<del>                                     </del>				X
Plans include essential personnel and their training (Guide, p 35)	X				
<ul> <li>Animal facility plans are approved by the institution and incorporated into overall response plan (Guide, p 35)</li> </ul>	X				
<ul> <li>Law enforcement and emergency personnel are provided a copy and integration with overall plan is in place (Guide, p 35)</li> </ul>	X				
3. IACUC	$\mathbf{A}^*$	M	S	C	NA
Meets as necessary to fulfill responsibilities (Guide, p 25) [must]	X				
<ul> <li>IACUC Members named in protocols or with conflicts recuse themselves from protocol decisions (Guide, p 26) [must]</li> </ul>	X				
<ul> <li>Continuing IACUC oversight after initial protocol approval is in place (Guide, p 33)</li> </ul>	X				
<ul> <li>IACUC evaluates the effectiveness of training programs (Guide, p 15)</li> </ul>	X				
4. IACUC Protocol Review - Special Considerations	<b>A</b> *	М	S	С	NA
<ul> <li>Humane endpoints are established for studies that involve tumor models, infectious diseases, vaccine challenge, pain modeling, trauma, production of monoclonal antibodies, assessment of toxicologic effects, organ or system failure, and models of cardiovascular shock (Guide, p 27)</li> </ul>	X				
For pilot studies, a system to communicate with the IACUC is in place (Guide, p 28)					X
<ul> <li>For genetically modified animals, enhanced monitoring and reporting is in place (Guide, p 28)</li> </ul>					X
					X
<ul> <li>Restraint devices are justified in the animal use protocols (Guide, p 29) [must]</li> </ul>		_			
<ul> <li>Restraint devices are justified in the animal use protocols (Guide, p 29) [must]</li> <li>Alternatives to physical restraint are considered (Guide, p 29)</li> </ul>					X
					XXX

	nimals that fail to adapt are removed from study ( <i>Guide</i> , <u>p 29</u> )					<b>)</b>
	ppropriate observation intervals of restrained animals are provided (Guide, p 29)					<b>)</b>
	eterinary care is provided if lesions or illness result from restraint ( <i>Guide</i> , <u>p 30</u> )  must					)
• E	xplanations of purpose and duration of restraint are provided to study personnel Guide, p 30)					)
• M	fultiple surgical procedures on a single animal are justified and outcomes evaluated Guide, p 30)					,
• M	lajor versus minor surgical procedures are evaluated on a case-by-case basis ( <i>Guide</i> , 30)					,
• M	Jultiple survival procedure justifications in non-regulated species conform to regulated pecies standards ( <i>Guide</i> , p 30)					
· A	nimals on food/fluid restriction are monitored to ensure nutritional needs are met Guide, p 31)					
• B	ody weights for food/fluid restricted animals are recorded at least weekly ( <i>Guide</i> , <u>p</u> 1)					
	Paily written records are maintained for food/fluid restricted animals ( <i>Guide</i> , <u>p 31</u> )					
<ul> <li>Pl</li> </ul>	harmaceutical grade chemicals are used , when available, for animal-related rocedures ( <i>Guide</i> , p 31)	х				ľ
N	lon-pharmaceutical grade chemicals are described, justified, and approved by IACUC Guide, p 31)	X				
• Îr	nvestigators conducting field studies know zoonotic diseases, safety issues, laws and egulations applicable in study area ( <i>Guide</i> , <u>p 32</u> )	X				
• D	Disposition plans are considered for species removed from the wild ( <i>Guide</i> , <u>p 32</u> )	X				
	oe-clipping only used when no alternative, performed aseptically and with pain relief <i>Guide</i> , p 75					
IACI	UC Membership and Functions	$\mathbf{A}^*$	М	S	С	N
	ACUC is comprised of at least 5 members, appointed by CEO (PHS Policy, <u>IV.A.3.</u> )	X				Т
• M	lembers include a veterinarian, a scientist, a nonscientist, and a nonaffiliated non-lab nimal user ( <i>Guide</i> , p 24) <sup>ii</sup>	Х				
• I/	ACUC authority and resources for oversight and evaluation of institution's program re provided ( <i>Guide</i> , p 14)	X				
	ACUC conducts semiannual evaluations of institutional animal care and use program PHS Policy, IV.B.)	X				
	conducts semiannual inspections of institutional animal facilities (PHS Policy, <u>IV.B.</u> )	X				
	ACUC organizationally reports to the Institutional Official (PHS Policy, <u>IV.A.1.b.</u> )	X				
• M	lethods for reporting and investigating animal welfare concerns are in place ( <i>Guide</i> , <u>p</u> 3) [must]					$\top$
	2/ [max]	X				
• R	eviews and investigates concerns about animal care and use at institution <sup>iii</sup> (PHS olicy, <u>IV.B.</u> )	X				
• Ri Po • Pi (F	eviews and investigates concerns about animal care and use at institution <sup>iii</sup> (PHS olicy, <u>IV.B.</u> ) rocedures are in place for review, approval, and suspension of animal activities <sup>iv</sup> PHS Policy, <u>IV.B.</u> )					
2: • R: • P: • P: (F	eviews and investigates concerns about animal care and use at institution <sup>iii</sup> (PHS olicy, <u>IV.B.</u> ) rocedures are in place for review, approval, and suspension of animal activities <sup>iv</sup> PHS Policy, <u>IV.B.</u> ) rocedures are in place for review and approval of significant changes to approved	X				
2:     R    P    P	eviews and investigates concerns about animal care and use at institution <sup>iii</sup> (PHS olicy, <u>IV.B.</u> ) rocedures are in place for review, approval, and suspension of animal activities <sup>iv</sup> PHS Policy, <u>IV.B.</u> ) rocedures are in place for review and approval of significant changes to approved ctivities (PHS Policy, <u>IV.B.</u> ) olicies are in place for special procedures (e.g., genetically modified animals, estraint, multiple survival surgery, food and fluid regulation, field investigations,	X X				
2:     R	eviews and investigates concerns about animal care and use at institution <sup>iii</sup> (PHS olicy, <u>IV.B.</u> ) rocedures are in place for review, approval, and suspension of animal activities <sup>iv</sup> PHS Policy, <u>IV.B.</u> ) rocedures are in place for review and approval of significant changes to approved ctivities (PHS Policy, <u>IV.B.</u> ) olicies are in place for special procedures (e.g., genetically modified animals, estraint, multiple survival surgery, food and fluid regulation, field investigations, gricultural animals) ( <i>Guide</i> , <u>p 27-32</u> ) equests for exemptions from major survival surgical procedure restrictions are made	X X				Ť
2:     R    R    P    R    R    R    R	Leviews and investigates concerns about animal care and use at institution (PHS olicy, IV.B.)  rocedures are in place for review, approval, and suspension of animal activities PHS Policy, IV.B.)  rocedures are in place for review and approval of significant changes to approved ctivities (PHS Policy, IV.B.)  olicies are in place for special procedures (e.g., genetically modified animals, estraint, multiple survival surgery, food and fluid regulation, field investigations, gricultural animals) (Guide, p 27-32)  Lequests for exemptions from major survival surgical procedure restrictions are made of USDA/APHIS* (Guide, p 30) [must]	x x x	M	s	C	
2:     R    P    P    P    P    P    P	Leviews and investigates concerns about animal care and use at institution (PHS olicy, IV.B.)  rocedures are in place for review, approval, and suspension of animal activities PHS Policy, IV.B.)  rocedures are in place for review and approval of significant changes to approved ctivities (PHS Policy, IV.B.)  olicies are in place for special procedures (e.g., genetically modified animals, estraint, multiple survival surgery, food and fluid regulation, field investigations, gricultural animals) (Guide, p 27-32)  Lequests for exemptions from major survival surgical procedure restrictions are made of USDA/APHIS* (Guide, p 30) [must]	x x x	M	s	C	
2:     R    P    P    P    P    P    P	Leviews and investigates concerns about animal care and use at institution (PHS olicy, IV.B.)  rocedures are in place for review, approval, and suspension of animal activities PHS Policy, IV.B.)  rocedures are in place for review and approval of significant changes to approved ctivities (PHS Policy, IV.B.)  olicies are in place for special procedures (e.g., genetically modified animals, estraint, multiple survival surgery, food and fluid regulation, field investigations, gricultural animals) (Guide, p 27-32)  equests for exemptions from major survival surgical procedure restrictions are made of USDA/APHIS* (Guide, p 30) [must]  UC Training NEW III IACUC members should receive:	x x x	M	S	С	
2:     Ro Po (F)     Po according to the control of	Leviews and investigates concerns about animal care and use at institution (PHS olicy, IV.B.)  rocedures are in place for review, approval, and suspension of animal activities PHS Policy, IV.B.)  rocedures are in place for review and approval of significant changes to approved ctivities (PHS Policy, IV.B.)  olicies are in place for special procedures (e.g., genetically modified animals, estraint, multiple survival surgery, food and fluid regulation, field investigations, gricultural animals) (Guide, p 27-32)  equests for exemptions from major survival surgical procedure restrictions are made o USDA/APHIS* (Guide, p 30) [must]  UC Training NEW (II IACUC members should receive:  Formal orientation to institution's program (Guide, p 17)	X X X	M	S	C	
2:     R    P    P    P    P    P    P	Reviews and investigates concerns about animal care and use at institution (PHS olicy, IV.B.)  rocedures are in place for review, approval, and suspension of animal activities (PHS Policy, IV.B.)  rocedures are in place for review and approval of significant changes to approved ctivities (PHS Policy, IV.B.)  olicies are in place for special procedures (e.g., genetically modified animals, estraint, multiple survival surgery, food and fluid regulation, field investigations, gricultural animals) (Guide, p 27-32)  equests for exemptions from major survival surgical procedure restrictions are made o USDA/APHIS* (Guide, p 30) [must]  UC Training NEW  II IACUC members should receive:  Formal orientation to institution's program (Guide, p 17)  Training on legislation, regulations, guidelines, and policies (Guide, p 17)	X X X A*	M	S	C	

o Promptly advises OLAW of serious/ongoing Guide deviations or PHS Policy noncompliance (NOT-OD-05-034)  o Institute must promptly advise OLAW of any suspension of an animal activity by the IACUC (NOT-OD-05-034)  Reports to U.S. Department of Agriculture (USDA) or Federal funding agency™  o Annual report to USDA contains required information including all exceptions/exemptions  Reporting mechanism to USDA is in place for IACUC-approved exceptions to the regulations and standards  Reports are filed within 15 days for failures to adhere to timetable for correction of significant deficiencies  Promptly reports suspensions of activities by the IACUC to USDA and any Federal funding agency  Records (PHS Policy, IV.E.)  o IACUC meeting minutes and semiannual reports to the IO are maintained for 3 years  Records of IACUC reviews of animal activities include all required information*  Records of IACUC reviews are maintained for 3 years after the completion of the study  Revermany Care (See also next section - Veterinary Care)  A* M S C NA  An arrangement for veterinarian(s) with training or experience in lab animal medicine is in place including backup veterinary care <sup>xi</sup> Veterinary access to all animals is provided (Guide, p. 14) [must]  Veterinarian provides consultation when pain and distress exceeds anticipated level in protocol (Guide, p. 14) [must]  Veterinarian provides consultation when pain and distress exceeds anticipated level in protocol (Guide, p. 15) [must]  Veterinarian(s) have experience and training in species used (Guide, p. 15) [must]  Veterinarian(s) have experience in facility administration/management (Guide, p. 15) [must]  Veterinarian(s) have experience in facility administration/management (Guide, p. 15) [must]  Veterinary (Shave experience in facility administration/management (Guide, p. 15) [must]  Veterinary (Shave experience in facility administration/management (Guide, p. 15) [must]  Veterinary (Shave experience in facility administration/management (Guide, p. 15) [must]  Veterinary (Shav			o Ongoing training/education ( <i>Guide</i> , <u>p 17</u> )	X				
Semiannual report to the IO (PHS Policy, IV.B.)  Submitted to IO every 6 months  Compiles program review and facility inspection(s) results (includes all program and facility deficiencies)  Includes minority IACUC views  Describes IACUC-approved departures from the Guide or PHS Policy and the reasons for each departure*  Distinguishes significant from minor deficiencies  Reports to OLAW (PHS Policy, IV.E.)  Annual report to USD and Solaw of serious/singuing Guide deviations or PHS Policy noncompliance (NOT-OD-05-034)  Reports to U.S. Department of Agriculture (USDA) or Federal funding agency*  Annual report to USDA contains required information including all exceptions/exemptions  Reports are filed within 15 days for failures to adhere to timetable for correction of significant deficiencies  Promptiv reports suspensions of activities by the IACUC to USDA and any Federal funding agency*  Records (PHS Policy, IV.E.)  ACUC reviews of animal activities include all required information*  Records of IACUC reviews of animal activities include all required information of the study  Records of IACUC reviews are maintained for 3 years after the completion of the study  Records of IACUC reviews are maintained for 3 years after the completion of the study  Records of IACUC reviews are maintained for 3 years after the completion of the study  Records of IACUC reviews are maintained for 3 years after the completion of the study  Records of IACUC reviews are maintained for 3 years after the completion of the study  Records of IACUC reviews are maintained for 3 years after the completion of the study  Records (PHS Policy, IV.E.)  Promotive reports are maintained for 3 years after the comp	7.	IA	CUC Records and Reporting Requirements <sup>vi</sup>	<b>A</b> *	М	S	С	NA
o Complies program review and facility inspection(s) results (includes all program and facility deficiencies)  o Includes minority IACUC views o Describes IACUC-approved departures from the <i>Guide</i> or PHS Policy and the reasons for each departure" o Distinguishes significant from minor deficiencies Includes a plan and schedule for correction for each deficiency identified   • Reports to OLAW (PHS Policy, IV.E.) o Annual report to OLAW documents program changes, dates of the semiannual program reviews and facility inspections and includes any minority views o Promptly advises OLAW of serious/gonging <i>Guide</i> deviations or PHS Policy Normal Program reviews and facility inspections and includes any minority views o Promptly advises OLAW of serious/gonging <i>Guide</i> deviations or PHS Policy Normal Program reviews and facility inspections and includes any minority views o Institute must promptly advise OLAW of any suspension of an animal activity by the IACUC (NOT-09-05-034) o Institute must promptly advise OLAW of any suspension of an animal activity by the IACUC (NOT-09-05-034) o Annual report to USDA contains required information including all exceptions/exemptions o Reporting mechanism to USDA is in place for IACUC-approved exceptions to the regulations and standards o Reports are filed within 15 days for failures to adhere to timetable for correction of significant deficiencies o Promptly reports suspensions of activities by the IACUC to USDA and any Federal funding agency o Records of IACUC reviews of animal activities by the IACUC to USDA and any Federal funding agency o Records of IACUC reviews of animal activities include all required information* o Records of IACUC reviews are maintained for 3 years o Records of IACUC reviews are maintained for 3 years after the completion of the study  8. Veterinary Care (See also next section - Veterinary Care)  • An arrangement for veterinarian(s) with training or experience in lab animal medicine is in place including backup veterinary care*  • Veterinarian provides consu		•						
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<ul> <li>Direct or delegated authority is given to the veterinarian to oversee all aspects of animal care and use (Guide, p 14) [must]</li> <li>Veterinarian provides consultation when pain and distress exceeds anticipated level in protocol (Guide, p 5) [must]</li> <li>Veterinarian provides consultation when interventional control is not possible (Guide, p 5) [must]</li> <li>If part time /consulting veterinarian, visits meet programmatic needs (Guide, p 14)</li> <li>Regular communication occurs between veterinarian and IACUC (Guide, p 14)</li> <li>Veterinarian(s) have experience and training in species used (Guide, p 15) [must]</li> <li>Veterinarian(s) have experience in facility administration/management (Guide, p 15)</li> <li>Personnel Qualifications and Training</li> <li>A* M S C NA</li> <li>All personnel are adequately educated, trained, and/or qualified in basic principles of laboratory animal science. Personnel included: [must]</li> <li>Veterinary/other professional staff (Guide, p 15-16)</li> <li>IACUC members (Guide, p 17)</li> </ul>		_						
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<ul> <li>If part time /consulting veterinarian, visits meet programmatic needs (Guide, p 14)</li> <li>Regular communication occurs between veterinarian and IACUC (Guide, p 14)</li> <li>Veterinarian(s) have experience and training in species used (Guide, p 15) [must]</li> <li>Veterinarian(s) have experience in facility administration/management (Guide, p 15)</li> <li>Personnel Qualifications and Training</li> <li>All personnel are adequately educated, trained, and/or qualified in basic principles of laboratory animal science. Personnel included: [must]</li> <li>Veterinary/other professional staff (Guide, p 15-16)</li> <li>IACUC members (Guide, p 17)</li> </ul>		•	Veterinarian provides consultation when interventional control is not possible (Guide, p					
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<ul> <li>Veterinarian(s) have experience and training in species used (Guide, p 15) [must]</li> <li>Veterinarian(s) have experience in facility administration/management (Guide, p 15)</li> <li>Personnel Qualifications and Training</li> <li>A* M S C NA</li> <li>All personnel are adequately educated, trained, and/or qualified in basic principles of laboratory animal science. Personnel included: [must]</li> <li>Veterinary/other professional staff (Guide, p 15-16)</li> <li>IACUC members (Guide, p 17)</li> </ul>		•	If part time /consulting veterinarian, visits meet programmatic needs (Guide, p 14)	X				
<ul> <li>Veterinarian(s) have experience and training in species used (Guide, p 15) [must]</li> <li>Veterinarian(s) have experience in facility administration/management (Guide, p 15)</li> <li>Personnel Qualifications and Training</li> <li>A* M S C NA</li> <li>All personnel are adequately educated, trained, and/or qualified in basic principles of laboratory animal science. Personnel included: [must]</li> <li>Veterinary/other professional staff (Guide, p 15-16)</li> <li>IACUC members (Guide, p 17)</li> </ul>		•		X				
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9. Personnel Qualifications and Training  • All personnel are adequately educated, trained, and/or qualified in basic principles of laboratory animal science. Personnel included: [must]  • Veterinary/other professional staff (Guide, p 15-16)  • IACUC members (Guide, p 17)								
All personnel are adequately educated, trained, and/or qualified in basic principles of laboratory animal science. Personnel included: [must]     Veterinary/other professional staff (Guide, p 15-16)     IACUC members (Guide, p 17)		•	veterinarian(s) have experience in facility administration/management (Guide, <u>p.15</u> )	^				
All personnel are adequately educated, trained, and/or qualified in basic principles of laboratory animal science. Personnel included: [must]     Veterinary/other professional staff (Guide, p 15-16)     IACUC members (Guide, p 17)	9.	Рe	rsonnel Qualifications and Training	<b>A</b> *	М	S	С	NA
<ul> <li>Veterinary/other professional staff (Guide, p 15-16)</li> <li>IACUC members (Guide, p 17)</li> </ul>		•						
o IACUC members ( <i>Guide</i> , <u>p 17</u> )			laboratory animal science. Personnel included: [must]					
o IACUC members ( <i>Guide</i> , <u>p 17</u> )			<ul> <li>Veterinary/other professional staff (Guide, p 15-16)</li> </ul>	X				
				X				
			Animal care personnel ( <i>Guide</i> , <u>p 16</u> )					X

	Research investigators, instructors, technicians, trainees, and students ( <i>Guide</i> , pp					
•	16-17) Continuing education for program and research staff provided to ensure high quality	X				
	care and reinforce training (Guide, pp 16-17)	X				
•	Training is available prior to starting animal activity (Guide, p 17)	X				
•	Training is documented ( <i>Guide</i> , p 15)	X				
•	Training program content includes: (Guide, p 17)	v	<u> </u>			
	Methods for reporting concerns (Guide, p 17)	X				
	Humane practices of animal care (e.g., housing, husbandry, handling) xii	X				
	<ul> <li>Humane practices of animal use (e.g., research procedures, use of anesthesia, pre- and post-operative care, aseptic surgical techniques and euthanasia (Guide, p</li> </ul>					
	17) XIII	X				
	<ul> <li>Research/testing methods that minimize numbers necessary to obtain valid results (PHS Policy, <u>IV.A.1.g.</u>)</li> </ul>	X				
	<ul> <li>Research/testing methods that minimize animal pain or distress (PHS Policy, IV.A.1.g.)</li> </ul>	Х				
	<ul> <li>Use of hazardous agents, including access to OSHA chemical hazard notices where applicable (Guide, p 20)</li> </ul>					x
	Animal care and use legislation ( <i>Guide</i> , <u>p 17</u> )	X				
	IACUC function ( <i>Guide</i> , <u>p 17</u> )	X				
	Ethics of animal use and Three R's (Guide, p 17)	Х				
	• • • • • • • • • • • • • • • • • • •					
10.	Occupational Health and Safety of Personnel	<b>A</b> *	М	S	С	NA
•	Program is in place and is consistent with federal, state, and local regulations ( <i>Guide</i> , <u>p 17</u> ) [must]	X				
•	Program covers all personnel who work in laboratory animal facilities (Guide, p 18)	X				
•	Changing, washing, and showering facilities are available as appropriate (Guide, p 19)	X				
•	Hazardous facilities are separated from other areas and identified as limited access ( $Guide$ , $p$ 19)	X				
•	Personnel training is provided based on risk (e.g., zoonoses, hazards, personal	X				
•	hygiene, special precautions, animal allergies) ( <i>Guide</i> , <u>p 20</u> )  Personal hygiene procedures are in place (e.g., work clothing, eating/drinking/smoking policies) ( <i>Guide</i> , <u>p 20</u> )					
•	Procedures for use, storage, and disposal of hazardous biologic, chemical, and physical					
	agents are in place (Guide, p 21)	X				
•	Personal Protective Equipment for the work area is appropriate and available ( <i>Guide</i> , <u>p</u> <u>21</u> )	X				
•	Program for medical evaluation and preventive medicine for personnel includes:					
	<ul> <li>Pre-employment evaluation including health history (Guide, p 22)</li> </ul>					X
	<ul> <li>Immunizations as appropriate (e.g., rabies, tetanus) and tests as appropriate (Guide, p 22)</li> </ul>	X				
	<ul> <li>Zoonosis surveillance as appropriate (e.g., Q-fever, tularemia, Hantavirus, plague)</li> <li>(Guide, p 23)</li> </ul>	X				
	<ul> <li>Procedures for reporting and treating injuries, including accidents, bites, allergies, etc. (Guide, <u>p 23</u>)</li> </ul>	X				
	<ul> <li>Promotes early diagnosis of allergies including preexisting conditions (Guide, p 22)</li> </ul>					X
	<ul> <li>Considers confidentiality and other legal factors as required by federal, state and local regulations (Guide, p 22) [must]</li> </ul>					X
	<ul> <li>If serum samples are collected, the purpose is consistent with federal and state laws (Guide, <u>p 22</u>) [must]</li> </ul>	X				
•	Waste anesthetic gases are scavenged ( <i>Guide</i> , <u>p 21</u> )					X
•	Hearing protection is provided in high noise areas (Guide, p 22)	X				
•	Respiratory protection is available when performing airborne particulate work ( <i>Guide</i> , p 22)					X
•	<u>p 22</u> ) Special precautions for personnel who work with nonhuman primates, their tissues or body fluids include:					_

		_				
	<ul> <li>Tuberculosis screening provided for all exposed personnel (Guide, p 23)</li> </ul>					X
	<ul> <li>Training and implementation of procedures for bites, scratches, or injuries associated with macaques (Guide, p 23)</li> </ul>					х
	<ul> <li>PPE is provided including gloves, arm protection, face masks, face shields, or goggles (Guide, p 21)</li> </ul>					х
	<ul> <li>Injuries associated with macaques are carefully evaluated and treatment implemented (Guide, p 23)</li> </ul>					х
•	Occupational safety and health of field studies is reviewed by OSH committee or office (Guide, p 32)	х				
11.	Personnel Security	<b>A</b> *	М	s	С	NA
•	Preventive measures in place include pre-employment screening, and physical and IT security ( $Guide$ , $p$ 23)	x				
12.	Investigating & Reporting Animal Welfare Concerns №	<b>A</b> *	М	s	С	NA
•	Methods for investigating and reporting animal welfare concerns are established (Guide, p 23) [must]	X				
•	Reported concerns and corrective actions are documented ( <i>Guide</i> , <u>p 24</u> )	X				
•	Mechanisms for reporting concerns are posted in facility and at applicable website with instructions ( <i>Guide</i> , p 24)	X				
	o Includes multiple contacts (Guide, p 24)	X				
	<ul> <li>Includes anonymity, whistle blower policy, nondiscrimination and reprisal protection (Guide, p 24)</li> </ul>	Х				

A = acceptable

**M** = minor deficiency

S = significant deficiency (is or may be a threat to animal health or safety)
C = change in program (PHS Policy <u>IV.A.1.a.-i.</u>) (include in semiannual report to IO and in annual report to OLAW)

NA = not applicable

# **Veterinary Care**

Date: 11/21/2019

	linical Care and Management NEW	<b>A</b> *	М	S	С	NA
•	[must]	X				
•	Veterinarian provides guidance to all personnel to ensure appropriate husbandry, handling, treatment, anesthesia, analgesia, and euthanasia ( <i>Guide</i> , <u>p 106</u> )	X				
•	Veterinarian provides oversight to surgery and perioperative care (Guide, p 106)					X
•	Veterinary care program is appropriate for program requirements ( <i>Guide</i> , pp 113-114)  Veterinarian(s) is familiar with species and use of animals and has access to medical and experimental treatment records ( <i>Guide</i> , p 114)	X	X			
•	Procedures to triage and prioritize incident reports are in place ( <i>Guide</i> , p 114)	^			X	
·	Procedures are in place to address:					
	<ul> <li>Problems with experiments to determine course of treatment in consultation with investigator(Guide, p 114)</li> </ul>				X	
	<ul> <li>Recurrent or significant health problems with the IACUC and documentation of treatments and outcomes (Guide, p 114)</li> </ul>				X	
	<ul> <li>Veterinary review and oversight of medical and animal use records (Guide, p 115)</li> </ul>				X	
•	Procedures established for timely reporting of animal injury, illness, or disease ( <i>Guide</i> , p 114) [must]				X	
•	Procedures established for veterinary assessment, treatment, or euthanasia ( <i>Guide</i> , <u>p</u> 114) [must]				X	
_	Veterinarian is authorized to treat, relieve pain, and/or euthanize ( <i>Guide</i> , <u>p 114</u> ) [must]				X	
Α	nimal Procurement and Transportation/Preventive Medicine	$\mathbf{A}^*$	М	S	С	N
•	Procedures for lawful animal procurement are in place (Guide, p 106) [must]	X				
•	Sufficient facilities and expertise are confirmed prior to procurement (Guide, p 106)	X				
•	Procurement is linked to IACUC review and approval (Guide, p 106)	X				
•	Random source dogs and cats are inspected for identification ( <i>Guide</i> , <u>p 106</u> )					X
•	Population status of wildlife species is considered prior to procurement ( <i>Guide</i> , <u>p 106</u> )	X				
•	Appropriate records are maintained on animal acquisition (Guide, p 106)	X				
•	Animal vendors are evaluated to meet program needs and quality ( <i>Guide</i> , <u>p 106</u> )	X				
•	Breeding colonies are based on need and managed to minimize numbers ( <i>Guide</i> , <u>p</u> <u>107</u> )	X				
•	Procedures for compliance with animal transportation regulations, including international requirements, are in place ( <i>Guide</i> , <u>p 107</u> ) [must]	X				
•	Transportation is planned to ensure safety, security and minimize risk ( <i>Guide</i> , <u>p 107</u> )	X				_
•	Movement of animals is planned to minimize transit time and deliveries are planned to ensure receiving personnel are available ( <i>Guide</i> , <u>pp 107- 108</u> )	X				
•	Appropriate loading and unloading facilities are available ( <i>Guide</i> , <u>p 109</u> )	X				
•	Environment at receiving site is appropriate ( <i>Guide</i> , <u>p 109</u> )	X				_
•	Policies in place on separation by species, source, and health status ( <i>Guide</i> , <u>pp 109</u> , <u>111-112</u> )	X				
•	Procedures in place for quarantine to include zoonoses prevention (Guide, p 110)	X				_
•	Quarantined animals from different shipments are handled separately or physically separated ( <i>Guide</i> , p 110)	X				
•	Procedures in place for stabilization/acclimation (Guide, pp 110-111)	X				
•	Policies in place for isolation of sick animals ( <i>Guide</i> , <u>p 112</u> )					X
•	Program is in place for surveillance, diagnosis, treatment and control of disease to include daily observation ( $Guide$ , $p$ 112)	X				
-	· · · · · · · · · · · · · · · · · · ·				X	1

. 3	Surgery	<b>A</b> *	М	S	С	N/
•						<b>X</b>
•	[must]					)
•	anesthetic and analgesic use, peri-operative care, recordkeeping) (Guide, p 116)					)
•	Aseptic surgery is conducted in dedicated facilities or spaces, unless exception justified and IACUC approved ( <i>Guide</i> , <u>p 116</u> )					)
•	minor ( <i>Guide</i> , pp 117-118)					)
•	For nonsurvival surgery, the site is clipped, gloves are worn and instruments and area are clean ( <i>Guide</i> , p 118)					)
•	Aseptic technique is followed for survival surgical procedures ( <i>Guide</i> , pp 118-119)					
•	-cc					,
•						,
•						)
•	Post-operative monitoring and care are provided by trained personnel and documented (e.g., thermoregulation, physiologic function, analgesia, infection, removal of skin closures) (Guide, pp 119-120)					)
	Pain, Distress, Anesthesia and Analgesia	<b>A</b> *	м	s	С	N
	Guidelines for assessment and categorization of pain, distress and animal wellbeing	_	141			T
_	are provided during training (Guide, p 121)	X				_
	(Guide, <u>p 121</u> )					2
•	(Guide, <u>p 122</u> )					2
•	Nonpharmacologic control of pain is considered as an element of postprocedural care ( <i>Guide</i> , <u>p 122</u> )					<b>)</b>
•	Procedures are in place to assure antinoception before surgery begins ( <i>Guide</i> , <u>p 122</u> )  [must]					2
•	Guidelines for selection and use of analgesics and anesthetics are in place and regularly reviewed and updated ( <i>Guide</i> , <u>p 122</u> )					)
•	Special precautions for the use of paralytics are in place to ensure anesthesia <sup>xiv</sup> (Guide, p 123)					2
E	Euthanasia	$\mathbf{A}^*$	М	s	С	N
•		X				
•	Standardized methods are developed and approved by the veterinarian and IACUC that avoid distress and consider animal age and species ( <i>Guide</i> , pp 123-124)				X	
•	Training is provided on appropriate methods for each species and considers psychological stress to personnel ( <i>Guide</i> , p 124)	X				
•	Procedures and training are in place to ensure death is confirmed ( <i>Guide</i> , <u>p 124</u> ) [must]	Х				
_	Drug Storage and Control NEW	<b>A</b> *	М	s	С	N
	Program complies with federal regulations for human and veterinary drugs(Guide, p  115) [must]	X				
•						
•		X				T
	expiration date (Guide, D 122) influsti	_^				

<sup>\*</sup> A = acceptable

**M** = minor deficiency

Semiannual Checklist v3/8/2012

8

**S** = significant deficiency (is or may be a threat to animal health or safety)

**C** = change in program (PHS Policy <u>IV.A.1.a.-i.</u>) (include in semiannual report to IO and in annual report to OLAW)

NA = not applicable

#### **NOTES:**

# **II. Semiannual Facility Inspection Checklist**

#### **Terrestrial Animal Housing and Support Areas**

Date: 11/21/2019

**Location: GEMMD Wetlabs** 

	<b>A</b> *	М	S	С	NA
• Location:	$\top$				X
o animal areas separate from personnel areas ( <i>Guide</i> , <u>p 134</u> )	+-				X
o separation of species (Guide, p 111)	+-				+
o separation by disease status (Guide, p 111)	_				X
<ul> <li>security and access control (Guide, p 151)</li> <li>Construction:</li> </ul>					X
o corridors ( <i>Guide</i> , <u>p 136</u> )	$\top$				X
o animal room doors ( <i>Guide</i> , <u>p 137</u> )	+				X
o exterior windows ( <i>Guide</i> , <u>p 137</u> )	+-				X
o floors ( <i>Guide</i> , p 137)	+				X
	+				X
" (0.1)	+				X
	+				X
o heating ventilation and air conditioning (Guide, p 139)	+				X
<ul> <li>power and lighting (Guide, p 141)</li> <li>noise control (Guide, p 142)</li> </ul>	+-				X
	+				X
o vibration control ( <i>Guide</i> , <u>p 142</u> )	+				X
<ul> <li>environmental monitoring (Guide, p 143)</li> <li>Room/Cage:</li> </ul>					^
o temperature and humidity ( <i>Guide</i> , <u>p 43</u> )	T				X
o ventilation and air quality ( <i>Guide</i> , p 45)					X
o illumination ( <i>Guide</i> , <u>p 47</u> )	+				X
o noise and vibration ( <i>Guide</i> , <u>p 49</u> )	+				X
Primary Enclosure:					
<ul> <li>space meets physiologic, behavioral xv, and social xvi needs (Guide, pp 51, 55-63)</li> </ul>					X
o secure environment provided ( <i>Guide</i> , p 51)					X
o durable, nontoxic materials in good repair and no risk of injury ( <i>Guide</i> , <u>p 51</u> )					X
o flooring is safe and appropriate for species ( <i>Guide</i> , <u>p 51</u> )					X
o adequate bedding and structures for resting, sleeping, breeding ( <i>Guide</i> , p 52)					X
o objective assessments of housing and management are made ( <i>Guide</i> , p 52)					X
o procedures for routine husbandry are documented ( <i>Guide</i> , p 52)					X
o socially housed animals can escape or hide to avoid aggression (Guide, p 55)	1				X
o cage height provides adequate clearance ( <i>Guide</i> , p 56)	$\top$				X
o animals express natural postures, can turn around, access food and water, and	+				
rest away from urine and feces ( <i>Guide</i> , <u>p 56</u> ) [must]	<del> </del>				X
<ul> <li>rationale<sup>xvii</sup> for Guide/USDA space exceptions approved by IACUC and based on performance indices (Guide, p 56)</li> </ul>					X
	+				X
o dogs and cats allowed to exercise and provided human interaction (Guide, p 58)	+-				X
<ul> <li>nonhuman primates are socially housed except for scientific, veterinary or</li> </ul>					/

0 1	frequency of bedding/substrate change ( <i>Guide</i> , <u>p 70</u> )	
0 (	cleaning and disinfection of microenvironment (Guide, pp 70-71)	
0 (	cleaning and disinfection of macroenvironment (Guide, p 72)	
0 6	assessing effectiveness ( <i>Guide</i> , <u>p 73</u> )	
Was	ste Disposal:	
0	procedures for collection ( <i>Guide</i> , <u>pp 73-74</u> )	
	procedures for storage and disposal ( <i>Guide</i> , <u>pp 73-74</u> )	
	hazardous wastes are rendered safe before removal from facility ( <i>Guide</i> , <u>pp 73-74</u> ) [must]	
0	animal carcasses ( <i>Guide</i> , pp 73-74)	
Pes	t Control:	
o I	regularly scheduled ( <i>Guide</i> , <u>p 74</u> )	
	documented program including control of rodent pests and insecticide use ( <i>Guide</i> , p 74)	
Eme	ergency, Weekend, and Holiday Animal Care:	
0	care provided by qualified personnel every day ( <i>Guide</i> , <u>p 74</u> )	
0	provision for accessible contact information (Guide, p 74)	
0 I	monitoring of backup systems ( <i>Guide</i> , <u>p 143</u> )	
0 '	veterinary care available after hours, weekends, and holidays ( <i>Guide</i> , pp 74,	
	114) [must]	
	a disaster plan that takes into account both personnel and animals ( <i>Guide</i> , <u>p 75</u> )	
Ide	ntification:	
	cage/rack cards contain required information ( <i>Guide</i> , <u>p 75</u> )	
	genotype information included and standardized nomenclature used when applicable ( <i>Guide</i> , p 75)	
Rec	ordkeeping:	
0	clinical records accessible and contain appropriate information ( <i>Guide</i> , pp 75-76)	
	records are provided when animals are transferred between institutions ( $Guide$ , $p$ $75$ )	
	eding Genetics and Nomenclature:	
	appropriate genetic records, management and monitoring procedures ( <i>Guide</i> , <u>p</u> 76)	
	phenotypes that affect wellbeing are reported to IACUC and effectively managed ( <i>Guide</i> , p 77)	
Sto	rage:	
0	adequate space for equipment, supplies, food, bedding and refuse ( <i>Guide</i> , <u>p 141</u> )	
	bedding in vermin-free area and protected from contamination(Guide, p 141)	
	food in vermin-free, temperature and humidity controlled area and protected from contamination ( <i>Guide</i> , <u>p 141</u> )	
0 I	refuse storage is separate ( <i>Guide</i> , <u>p 141</u> )	
(	carcass and animal tissue storage is separate, refrigerated below 7°C and cleanable ( <i>Guide</i> , <u>p 141</u> )	
Pers	sonnel:	
	adequate space for locker rooms, administration and training (Guide, p 135)	

**A** = acceptable

**M** = minor deficiency

S = significant deficiency (is or may be a threat to animal health or safety)
C = change in program (PHS Policy <u>IV.A.1.a.-i.</u>) (include in semiannual report to IO and in annual report to OLAW)

**NA** = not applicable

# Aquatic Animal Housing and Support Areas

Date: 11/21/2019 Location: GEMMD Wetlabs

		$\mathbf{A}^*$	М	s	С	NA
•	Location:	v				Т
	o animal areas separate from personnel areas (Guide, p 134)	X				$\vdash$
	o separation of species ( <i>Guide</i> , <u>p 111</u> )	X				
	o separation by disease status (Guide, p 111)	X				
•	o security and access control ( <i>Guide</i> , p 151)  Construction:	X				
•	.1. (0.1)					X
						X
						X
	o exterior windows ( <i>Guide</i> , p 137)	X				^
	o floors ( <i>Guide</i> , pp 137, 150)	X				
	o drainage (Guide, pp 138, 150)	_	X			
	o walls and ceilings ( <i>Guide</i> , pp 138, 150)	v	^			$\vdash$
	o heating ventilation and air conditioning ( <i>Guide</i> , pp 139, 150-151)	X				
	o power and lighting ( <i>Guide</i> , pp 141, 150)	X				-
	o noise control (Guide, p 142)	X				
	o vibration control ( <i>Guide</i> , <u>p 142</u> )	X				-
	o environmental monitoring (Guide, p 143)	X				
•	Water Quality:	v				Τ
	<ul> <li>standards for acceptable quality are established (<i>Guide</i>, <u>p 78</u>)</li> <li>chlorine, chloramines, chemical, and reactive bioproducts are removed or</li> </ul>	X				
	neutralized prior to use in aquatic systems ( <i>Guide</i> , pp78, 86) [must]	X				
•	Life Support System:					
	<ul> <li>water source is based on appropriate controls and research requirements (Guide, p 79)</li> </ul>	х				
	o biofilter is of sufficient size to process bioload (Guide, p 80) [must]					X
•	Temperature, Humidity and Ventilation/Illumination/Noise and Vibration:					
	o temperature and humidity ( <i>Guide</i> , pp 43, 80-81)	X				
	o ventilation and air quality ( <i>Guide</i> , pp 45, 81)	Х				
	o illumination ( <i>Guide</i> , pp 47, 81)	X				
	o noise and vibration ( <i>Guide</i> , pp 49, <u>81</u> )	X				
•	Primary Enclosure:					
	o allows for normal physiological and behavioral needs (Guide, p 82)	X				
	o allows social interaction for social species (Guide, p 82)	X				
	o provides a balanced, stable environment ( <i>Guide</i> , p 82)	X				
	o provides appropriate water quality and monitoring ( <i>Guide</i> , <u>p 82</u> )	X				
	o allows access to food and waste removal ( <i>Guide</i> , p 82)	X				
	o restricts escape and entrapment (Guide, p 82)	X				
	allows undisturbed observation (Guide, p 82)	X				
	o constructed of nontoxic materials ( <i>Guide</i> , <u>p 82</u> )	X				$\vdash$
		X				$\vdash$
	<ul> <li>prevents electrical nazards (Guide, p.82)</li> <li>space needs of species are evaluated by IACUC during program evaluations and</li> </ul>	_				$\vdash$
	facility inspections (Guide, p 83)	X				
	racine, mapageria (carac) pos					
•	Environmental Enrichment, Social Housing, Behavioral and Social Manageme	nt:				

	o semi-aquatic reptiles are provided terrestrial areas ( <i>Guide</i> , <u>p 83</u> )		X
	<ul> <li>handling is kept to a minimum and appropriate techniques are in place at facility or protocol level (Guide, p 84)</li> </ul>	X	
	on protocorrever (Guide, <u>p. 64</u> ) onets are cleaned, disinfected and managed to avoid contamination of systems	^	
	(Guide, p 84)	X	
•	Food:		
	o storage to prevent contamination, preserve nutrients and prevent pests ( <i>Guide</i> , $\underline{p}$ 84)	X	
	o delivery ensures access to all , minimizing aggression and nutrient loss ( <i>Guide</i> , <u>p</u> 84)	X	
	<ul> <li>storage times are based on manufacturer recommendations or accepted practice (Guide, p 84)</li> </ul>	X	
	o a nutritionally complete diet is provided ( <i>Guide</i> , p 84)	X	
•	Substrate:	71	
	o amount, type and presentation of substrate is appropriate for the system and the		
	species (Guide, p 85)		X
•	Sanitation, Cleaning and Disinfection		
	<ul> <li>frequency of tank/cage cleaning and disinfection is determined by water quality, permits adequate viewing and health monitoring (<i>Guide</i>, <u>p 86</u>)</li> </ul>		>
	o cleaning and disinfection of macroenvironment ( <i>Guide</i> , p. 86)		<b>X</b>
•	Waste Disposal:		
	o procedures for collection ( <i>Guide</i> , pp 73-74)	X	
	o hazardous wastes are rendered safe before removal from facility ( <i>Guide</i> , pp 73-		
	74) [must]	X	
•	o animal carcasses ( <i>Guide</i> , pp 73-74) <b>Pest Control:</b>	X	
	o regularly scheduled ( <i>Guide</i> , <u>p 74</u> )		<b>X</b>
	o documented program including control of pests and insecticide use ( <i>Guide</i> , p 74)		×
•	Emergency, Weekend, and Holiday Animal Care:		
	o care provided by qualified personnel every day ( <i>Guide</i> , pp 74, 87)	X	
	<ul> <li>provision for accessible contact information (Guide, pp 74, 87)</li> </ul>	X	
	o emergency response plans in place to address major system failures ( <i>Guide</i> , <u>87</u> )	X	
	o veterinary care available after hours, weekends, and holidays ( <i>Guide</i> , pp 74, 114)		
	[must]	X	
•	[must] Identification:	x	
•	Identification:	x	
•	Identification:  o cage/tank cards contain required information ( <i>Guide</i> , pp 75, 87)		
•	Identification:  o cage/tank cards contain required information ( <i>Guide</i> , pp 75, 87)		<b>X</b>
•	<ul> <li>Identification:</li> <li>cage/tank cards contain required information (<i>Guide</i>, pp 75, 87)</li> <li>genotype information included and standardized nomenclature used when</li> </ul>		)
	<ul> <li>Identification:</li> <li>cage/tank cards contain required information (<i>Guide</i>, pp 75, 87)</li> <li>genotype information included and standardized nomenclature used when applicable (<i>Guide</i>, pp 75, 87)</li> </ul>		
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	<ul> <li>Identification:         <ul> <li>cage/tank cards contain required information (Guide, pp 75, 87)</li> <li>genotype information included and standardized nomenclature used when applicable (Guide, pp 75, 87)</li> </ul> </li> <li>Recordkeeping:         <ul> <li>water quality parameters and frequency of testing recorded (Guide, p 88)</li> <li>records kept on feeding, nonexpired food supplies, live cultures (Guide, p 88)</li> </ul> </li> </ul>	X	)
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A = acceptable

M = minor deficiency

S = significant deficiency (is or may be a threat to animal health or safety)

C = change in program (PHS Policy IV.A.1.a.-i.) (include in semiannual report to IO and in annual report to OLAW) Semiannual Checklist v3/8/2012

**NA** = not applicable

## Cagewash

Date: 11/21/2019

**Location: GEMMD Wetlabs** 

		$\mathbf{A}^*$	М	s	С	NA
• Co	onstruction and Operation:					
0		X				
0	cage-washing equipment meets need (Guide, p 143)					X
0	doors, windows, floors, drainage, walls, ceilings (Guide, pp 136-138)					X
0	convenient to animal areas/waste disposal (Guide, p 143)					X
0	ease of access (including door size) facilitates use (Guide, p 143)	X				
0	sufficient space for staging and maneuvering ( <i>Guide</i> , p 143)	X				
0	safety precautions/clothing/equipment used for waste disposal/prewash/acid wash (( <i>Guide</i> , p 143)	х				
0	traffic flow clean to dirty with no contamination of clean equipment by dirty equipment and appropriate air pressurization (Guide, p 143)					x
0	insulation and/or sound attenuation present as needed (Guide, p 143)					X
0	utilities are appropriate ( <i>Guide</i> , <u>p 143</u> )	X				
0	ventilation meets heat and humidity load ( <i>Guide</i> , p 143)	X				
0	safety features (e.g., SOPs, warning signs, eyewash stations) are in use ( <i>Guide</i> , p 143)	х				
0	functioning safety devices to prevent entrapment in washer/sterilizers ( <i>Guide</i> , <u>p</u> 143)					х
0	cage wash temperatures are monitored and records are available (Guide, p 73)					X
0	appropriate clean cage storage ( <i>Guide</i> , <u>p 141</u> )	X				

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NA = not applicable

# **Special Facilities: Aseptic Surgery**

Date: 11/21/2019

**Location: GEMMD Wetlabs** 

		$\mathbf{A}^*$	М	S	С	N
•	General Considerations:					
	o location minimizes traffic/contamination (Guide, p 144)					
	<ul> <li>functional components (surgical support, animal preparation, surgeon scrub, operating room, postoperative recovery) are designed and separated (physically or otherwise) (<i>Guide</i>, <u>p 144</u>)</li> </ul>					
	<ul> <li>appropriate drug storage, control, expiration date monitoring (Guide, pp 115, 122)</li> </ul>					
	o safe sharps disposal system ( <i>Guide</i> , <u>p 74</u> )					
	o adequate records of anesthesia and perioperative care (Guide, p 122)					
•	o aseptic procedures in use for all survival surgery (Guide, pp 118-119)  Operating Room:					
	o effective contamination control procedures (Guide, p 144)					T
	o effective cleaning procedures/dedicated tools ( <i>Guide</i> , p 145)					Ī
	o interior surfaces smooth and impervious to moisture (Guide, p 145)					Ť
	HVAC system meets <i>Guide</i> requirements ( <i>Guide</i> , <u>p 145</u> )					Ť
	o lighting safe and appropriate ( <i>Guide</i> , p 145)					Ť
	o outlets safe and appropriate ( <i>Guide</i> , p 145)					Ť
	o scavenging of anesthetic gases implemented (Guide, p 145)					Ī
•	Surgical Support:					_
	o facility for washing, sterilizing, storing instruments and supplies ( <i>Guide</i> , p 145)					T
	o autoclave monitoring procedures are implemented ( <i>Guide</i> , pp 119, 145)					Ť
	o storage of autoclaved materials maintains sterility (Guide, p 145)					Τ
	o cold sterilization procedures are appropriate (Guide, p 119)					Ť
•	Animal Preparation: contains large sink to facilitate cleaning of animal and operative site ( <i>Guide</i> , p 145)					İ
•	Surgeon Scrub: outside operating room, non-hand-operated sink (Guide, p 145)					Ī
•	Postoperative Recovery: allows adequate observation, easily cleaned, supports physiologic functions, minimizes risk of injury ( <i>Guide</i> , p 145)					İ
•	Dressing Area: place for personnel to change (Guide, p 145)					T

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NA = not applicable

# Special Facilities: Procedure Areas, Non-survival Surgeries, Laboratories, Rodent Surgeries, Imaging, Whole Body Irradiation, Hazardous Agent Containment, Behavioral Studies

#### Date: Location:

		$\mathbf{A}^*$	М	S	С	N
•	General Considerations:					
	<ul> <li>labs used to house animals only when scientifically required and limited to minimum period necessary (Guide, p 134)</li> </ul>					
	o drug storage, control, and expiration dates (Guide, pp 115, 122)					
	o sharps disposal ( <i>Guide</i> , <u>p 74</u> )					Γ
	o anesthetic monitoring ( <i>Guide</i> , p 120)					Γ
	o scavenging of anesthetic gases ( <i>Guide</i> , p 21)					T
	<ul> <li>safety features (e.g., SOPs, safety signs, eyewash stations, secure gas cylinders) are in place (Guide, p 19)</li> </ul>					
	o carcass disposal ( <i>Guide</i> , pp 73-74)					
•	Additional Concerns for Survival Surgery: (rodent and minor procedures only)					
	<ul> <li>rodent survival surgery clean and uncluttered, not used for anything else during surgery (Guide, p 144)</li> </ul>					
	o records of peri-operative care (Guide, p 120)					ļ
	o aseptic procedures (Guide, pp 118-119)					
	o autoclave monitoring procedures (Guide, pp 119, 145)					
	o storage of autoclaved materials ( <i>Guide</i> , p 145)					
	o cold sterilization procedures are appropriate (Guide, p 119)					Ι
•	Imaging/Whole Body Irradiation: NEW					Τ
	o location of resource limits contamination risk (Guide, p 147)					
	o appropriate transportation methods are in place (Guide, p 147)					Γ
	o gas anesthesia provision, scavenging and monitoring are appropriate ( <i>Guide</i> , <u>p</u> <u>147</u> )					Ī
	o appropriate sensors and ventilation are provided for cryogen gases ( <i>Guide</i> , <u>p</u> <u>147</u> ) [must]					
	o imaging console is located away from radiation source (Guide, p 147)					Γ
•	Hazardous Agent Containment: №₩					
	<ul> <li>facility adheres to APHIS, USDA and CDC Select Agent Regulations and other federal, state and local regulations including security measures (<i>Guide</i>, p 148)</li> <li>[must]</li> </ul>					
•	Behavioral Studies: 🏋					
	<ul> <li>facility minimizes airborne transmission of noise and ground-borne transmission of vibration (Guide, p 149)</li> </ul>					
	o floor coverings reduce sound transmission (Guide, p 149)					
	o testing equipment allows for surface disinfection (Guide, p 150)					
	<ul> <li>components that cannot be cleaned are not in ready contact with animals and kept covered when not in use (Guide, p 150)</li> </ul>					
	o housing areas are contiguous with testing areas when appropriate (Guide, p 150)					Γ

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NA = not applicable

## III. Semiannual Program Review and Facility Inspection Report

Date: 11/21/2019

Members in Attendance: Jim Harvey, Exemption 6Exemption 6 Exemption 6 , Leslie Jarrell (via phone/Facetime) and

Deficiency Category*	<b>√</b>	Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date Complete
M		Wetlab	MS222 and hCG need to be pharmaceutical grade. Replace with pharmaceutical grade.	Exemption 6 Exemption 6 Exemption 6 Exemption 6	Still working on contracting a Vet	
M		T22/23	Wooden box step at T22/23 need to be repainted/sealed or the top replaced.  Replace with plastic	Jim Harvey (JH)	Repainted and resealed	12/10/2019
M		Wetlab	Columns supporting head boxes are showing serious rust. Will try to replace columns.	Exemption 6  (Wetlab manager)	Waiting on funding for Facilities	
WishList		Wetlab	Head Boxes in one section are crowded. Will try to uncrowd the boxes and use newer material to match the rest of the head boxes.			
WishList		Wetlab	Water Storage Tanks are due for cleaning. Need funds to have this done.			
WishList		Wetlab	Water testing. Need funds to test for heavy metals.			

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**NA** = not applicable

Check if repeat deficiency

Semiannual Checklist 19 v3/8/2012

#### **IV.** Endnotes

<sup>1</sup> The PHS Policy requires that Assured institutions comply with the regulations (9 CFR, Subchapter A) issued by the U.S. Department of Agriculture (USDA) under the Animal Welfare Act, as applicable. The endnotes below are specific USDA regulatory requirements that differ from or are in addition to the PHS Policy. This list is not intended to be all inclusive. For additional information please refer to 9 CFR Subchapter A - Animal Welfare.

- 2.31(b)(2) "The Committee shall be composed of a Chairman and at least two additional members;... at least one shall not be affiliated in any way with the facility...such person will provide representation for general community interests in the proper care and treatment of animals." [PHS policy requires 5 members]
- iii 2.32(c)(4) "...No facility employee, Committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulation or standards under the Act." [USDA requirement additional to PHS Policy]
- iv 2.31(d)(5) "...shall conduct continuing reviews of activities...not less than annually." [PHS Policy requires a complete new review every 3 years utilizing all the criteria for initial review]
- <sup>v</sup> 2.31(d)(1)(x) "...no animal will be used in more than one major operative procedure from which it is allowed to recover unless...(it is) justified for scientific reasons...(or is) required as routine veterinary procedure...or other special circumstances as determined by the Administrator on an individual basis." [this last point is an additional USDA justification for multiple survival surgeries]
- vi 2.36 "...each reporting facility shall submit an annual report to the APHIS, AC sector supervisor for the State where the facility is located on or before December 1 of each calendar year." [The USDA annual report has a list of requirements which differ from PHS annual report]
- vii 2.36(b)(3) "...exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the IACUC. A summary of all such exceptions must be attached to the facility's annual report." [Refers to USDA annual report]
- viii 2.31(c)(3) "...Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected shall be reported in writing within 15 business days by the IACUC, through the institutional official, to APHIS and any Federal agency funding that activity." [PHS Policy requires prompt reporting to OPRR of serious or continuing noncompliance with the PHS Policy or serious deviations from the provisions of the *Guide*]
- ix 2.36 "...each reporting facility shall submit an annual report to the APHIS, AC sector supervisor for the State where the facility is located on or before December 1 of each calendar year." [The USDA annual report has a list of requirements which differ from PHS annual report]
- x In addition to PHS requirements for IACUC review/application for funding, USDA regulations require: 2.31(d)(1)(ii) "The principal investigator (PI) consider alternatives to procedures that cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources...used to determine that alternatives were not available."
  - 2.31(d)(1)(iii) "The PI has provided written assurance that the activities do not unnecessarily duplicate previous experiments."
  - 2.31(d)(1)(iv) "Procedures that may cause more than momentary or slight pain or distress to the animals will:
    - involve in their planning, consultation with the attending veterinarian or his or her designee; [PHS Policy does not specify veterinary consultation]
    - not include paralytics without the use of anesthesia;"

ii Part 2 Subpart C - Research Facilities

- 2.31(d)(1)(x) "No animal will be used in more than one major operative procedure from which it is allowed to recover, unless justified for scientific reasons by the principal investigator, in writing..."
- xi 2.33(a)(1) "In the case of a part-time attending veterinarian or consultant arrangements, the formal arrangements shall include a written program of veterinary care and regularly scheduled visits to the research facility." [USDA requirement additional]
- xii 2.32(c) "Humane methods of animal maintenance and experimentation, including the basic needs of each species, proper handling and care for the various species of animals used by the facility, proper pre-procedural and post-procedural care of animals, and aseptic surgical methods and procedures."
- xiii 2.32(c) additional specifications include:
- "proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility"
- "methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility..."
- "utilization of services (e.g., National Agricultural Library, National Library of Medicine) to provide information on appropriate animal care and use, alternatives to the use of live animals in research , that could prevent unintended and unnecessary duplication of research involving animals, and regarding the intent and requirements of the Act." [USDA training specifications are more detailed than PHS Policy].
- xiv 2.31(d)(iv)(C) "Procedures that may cause more than momentary or slight pain or distress to the animals will...not include the use of paralytics without anesthesia."
- <sup>xv</sup> Part 3 Subpart A 3.8 "...research facilities must develop, document, and follow an appropriate plan to provide dogs with the opportunity for exercise. In addition the plan must be approved by the attending veterinarian. The plan must provide written standard procedures..."
- xvi Part 3 Subpart D 3.81 "...research facilities must develop, document, and follow an appropriate plan for environment enhancement adequate to promote the psychological well-being of nonhuman primates."
- xvii Part 3 Subpart A 3.6(c)(1) "Each dog housed in a primary enclosure must be provided with a minimum amount of floor space, calculated as follows: (length of dog in inches  $+6)^2/144$  = required floor space in square feet)."
- Part 3 Subpart D 3.80 (b) "Primary enclosures [for nonhuman primates] must meet the minimum space requirements provided in this subpart."
- In situations where the USDA regulations and the *Guide* differ with respect to space requirements, the larger of the two must be followed.